Attorney Docket No. 13971US04

IN THE UNITED STATES
PATENT AND TRADEMARK OFFICE

Appellants: Grooms, *et al.*	**CERTIFICATE OF MAILING**
Serial No.: 09/905,683	**Express Mail No.:** EV 726847631 US
Filed: July 13, 2001	**Date:** March 12, 2007
For: "Multi-Component Cortical Bone Assembled Implant" (Title As Amended)	
Group Art Unit: 3738	
Examiner: Bruce Edward Snow	

APPELLANTS' BRIEF ON APPEAL UNDER 37 CFR § 1.192 TO THE BOARD OF PATENT APPEALS AND INTERFERENCES

Mail Stop Appeal Brief-Patents
Commissioner for Patents
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Dear Sir:

In response to the Official Action of March 15, 2006, rejecting all pending claims (claims 111-118 and 120-136), and the Notice of Appeal filed on September 11, 2006, for which a Brief on Appeal under 37 C.F.R. § 1.192 was due on November 11, 2006, now extended four (4) months to March 12, 2007 (March 11, 2007 being a Sunday), the Appellants hereby file this Brief on Appeal, appealing the bases for final rejection of all the pending claims (*i.e.*, claims 111-118 and 120-136).

The Appellants respectfully request that the Board of Patent Appeals and Interferences reverse the pending rejections of claims 111-118 and 120-136 of the present application.

I. REAL PARTY IN INTEREST

The real party in interest in the above-identified application is Regeneration Technologies, Inc. a Florida corporation, having a principal place of business at 11621 Research Circle, Alachua FL 32615.

II. RELATED APPEALS AND INTERFERENCES

There is a pending appeal regarding U.S. Patent Application Serial No. 10/387,322, which is a continuation-in-part of the instant application, and thus may directly affect, be affected by, or have a bearing on the Board of Patent Appeals and Interferences' decision in the pending appeal. The Brief on Appeal with respect to U.S. Patent Application Serial No. 10/387,322 was filed on November 22, 2006. A Notice of Non-Compliant Brief was sent on January 5, 2007, and a response including an Amended Brief on Appeal was filed on February 5, 2007.

There has been no decision rendered by the Board in the pending appeal regarding U.S. Patent Application Serial No. 10/387,322. Consequently, there are no materials attached in the Related Proceedings Appendix.

III. STATUS OF THE CLAIMS

The present application was filed on July 13, 2001 with claims numbered 1-58.[1] A Notice to File Missing Parts of Nonprovisional Application was mailed on December 10, 2001,[2] to which a Response was filed on March 11, 2002.[3] A Preliminary Amendment was filed that was received by the Office of Initial Patent Examination on January 30, 2002, in which claims 1-58 were canceled and claims 59-110 were added.[4] A restriction requirement under 35 U.S.C. §121 was mailed on

[1] Exhibit 1, Evidence Appendix.

[2] Exhibit 2, Evidence Appendix.

[3] Exhibit 3, Evidence Appendix

[4] Exhibit 4, Evidence Appendix

August 6, 2003.[5] A Response to the restriction requirement was filed on September 11, 2003,[6] and an Office Communication stating that the Response was not fully responsive to the restriction requirement was mailed on October 8, 2003.[7] In response, on February 16, 2004, Appellants elected the species of the embodiment of Figure 7, canceled claims 59-110, and added claims 111-128.[8] Claim 119 was withdrawn from consideration as being drawn to non-elected inventions or species in the Office Action mailed on March 16, 2004.[9] Additionally, in the Office Action mailed on March 16, 2004, claims 111-118 and 120-128 received a provisional double patenting rejection, and were rejected under 35 U.S.C. §103(a).[10]

In an Amendment and Response dated September 16, 2004, claims 111-113 were amended.[11] In a non-final Office Action mailed December 15, 2004, the provisional double patenting rejection was maintained, claim 117 was rejected under 35 U.S.C. §112, second paragraph, claims 111-118, 120-123 and 126-127 were rejected under 35 U.S.C. §102(b), and claims 111-118 and 120-128 were rejected under 35 U.S.C. §103(a).[12]

In an Amendment and Response dated April 13, 2005, claims 111 and 117 were amended.[13] A final Office Action was then mailed on June 17, 2005, in which the provisional double patenting rejection was maintained, claims 111-118, 120-123 were rejected under 35 U.S.C. §102(b), and claims 111-118 and 120-128 were rejected under 35 U.S.C. §103(a).[14]

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[5] Exhibit 5, Evidence Appendix.

[6] Exhibit 6, Evidence Appendix

[7] Exhibit 7, Evidence Appendix

[8] Exhibit 8, Evidence Appendix

[9] Exhibit 9, at p. 2, Evidence Appendix.

[10] Id. at pp.2-4.

[11] Exhibit 10, at p. 9, Evidence Appendix.

[12] Exhibit 11, at pp. 2-7, Evidence Appendix.

[13] Exhibit 12, at pp. 2-3, Evidence Appendix

[14] Exhibit 13, at pp. 3-8, Evidence Appendix.

A Request for Continued Examination was filed together with an Amendment and Response on December 19, 2005.[15] In the Amendment and Response filed with the Request for Continued Examination, claim 111 was amended and claims 129-136 were added by copying the previously presented claims 111-118 and amending the independent claim.[16] Claims 129-136 thus constituted an amended form of previously rejected claims 111-118.

A Non-Final rejection was mailed on March 15, 2006, in which the provisional double patenting rejection was withdrawn, claims 111-118, 120-123 and 129-136 were rejected under 35 U.S.C. §102(b), and claims 111-118 and 120-136 were rejected under 35 U.S.C. §103(a).[17] In accordance with 35 U.S.C. §134, each of the pending clams having been twice rejected, a Notice of Appeal was then filed on September 11, 2006.[18]

In the present application, claims 111-118 and 120-136 are pending and have been twice rejected. All presented amendments to these claims have been entered. The text of pending claims claims 111-118 and 120-136 is attached in the Claims Appendix filed herewith.

IV. SUMMARY OF THE AMENDMENTS

No amendments to the pending claims were submitted after the Office Action mailed March 15, 2006.

V. SUMMARY OF THE CLAIMED SUBJECT MATTER

Pending independent claim 111 is directed to "[a]n assembled bone implant suitable for implantation into a patient comprising: a first cortical bone portion; a second cortical bone portion; said first cortical bone portion and said second cortical bone portion having one or more circular through holes sized and positioned for receiving one or more retention pins for connecting said first cortical bone portion to said second cortical bone portion; and one or more retention pins of appropriate diameter for fitting said through holes and connecting said first

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[15] Exhibit 14, Evidence Appendix.

[16] Id. at pp.2-5, and 6.

[17] Exhibit 15, at pp. 2 and 6-10, Evidence Appendix.

[18] Exhibit 16, Evidence Appendix.

cortical bone portion to said second cortical bone portion and forming said assembled bone implant as a unitary body outside of said patient, said assembled bone implant being suitable for implantation into said patient."[19]

Support for independent claim 111 can be found throughout the specification of the application as filed. For example, the Field of the Invention section of the application as filed states, "This invention relates to a cortical bone implant for use in cervical Smith-Robinson vertebral fusion procedures, as well as methods for the manufacture and use thereof. Furthermore, this application relates to an assembled implant comprised of two or more individual segments fastened together."[20] As another example, the Detailed Description section of the application as filed provides the following description:

> For example, in a first such alternate method, implants of this invention are produced and then stacked to provide a unitary implant of the desired height dimensions. Such stacked implants may be maintained in a unitary association by drilling appropriate holes through the height of the implant, and inserting therein appropriate retention pins made from any desirable material, including cortical bone, bioabsorbable synthetic polymer, titanium or other metallic retention pins.[21]

Additional support can be found, for example, at p. 2, lines 22-24 ("cortical bone implant for use in achieving anterior cervical fusions when implanted according to the Smith-Robinson procedure "); at p. 4, lines 15-19 ("shipment to physicians for use in implantation procedures"); at p. 4, lines 23-25 ("The implant is preferably formed from cortical bone"); at p. 6, lines 15-17 ("bringing halves of the implant into juxtaposition with each other"); at p. 19, lines 12-17 ("two implants 901 and 902 are retained in registered juxtaposition to form the implant 900"); at p. 19, lines 20-24 ("holes may be formed in each half, and the halves maintained in contact by forcing pins through the holes"); at originally filed claims 11-16, 25-26, and 49-50; and at the Abstract at p. 37, lines 3-8 ("An implant composed substantially of cortical bone is provided").[22]

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[19] Claim 111, Claims Appendix.

[20] Exhibit 1, at p. 1, lines 18-21, Evidence Appendix. (Emphasis added).

[21] Exhibit 1, at p. 6, lines 6-11, Evidence Appendix. (Emphasis added).

[22] Exhibit 1, Evidence Appendix.

Further support for claim 111 can be found at Figures 7A and 7B, and the corresponding discussion thereof in the specification at pages 18-19:

> In FIG. 7, there is shown a further aspect of this invention in which an implant, either machined as described above, or prior to said machining, is further machined so as to allow stacking thereof to achieve implants of various heights. <u>Commencing from a blank cortical plug</u> at the stage shown in FIG. 2D has the advantage that if breakage of the implant occurs during machining, this will likely occur prior to completion of all of machining steps. According to this embodiment of the invention, <u>two implant blanks of known height are selected such that a unitary implant</u> composed of both starting implants can be produced of a new desired height (e.g. a 6 mm high implant may be stacked with a 7 mm high implant to produce a 13 mm implant). Each implant blank is placed in a drill jig, and by means of a drill press or like means, <u>holes are drilled through the implants</u>. With the implants still in the jig, the jig is placed on the table of an arbor press. <u>Pins</u>, composed of cortical bone, resorbable but strong biocompatible synthetic material, or metallic pins <u>of the appropriate diameter are then impelled into the holes in the implants such that the implants are formed into a unitary body by these pins</u>. In order to encourage bony ingrowth, channels may be cut into the adjacent surfaces of the implants. The embodiment shown in FIG. 7A is a top view of an implant 700 into which <u>four holes 701-704</u> have been drilled. In FIG. 7B, there is shown the juxtaposition of two implants 700A and 700B, with the drilled holes 701-704 in register to receive pins for maintaining the implants in register. In this view, the adjacent surfaces 710A and 710B have not been inscribed with teeth, while the surfaces 711A and 711B have been so inscribed. Based on this disclosure, those skilled in the art will recognize that a number of variations and modifications may be made to stack various forms of bone implants, or to maintain such implants in register with each other. These modifications are to be considered within the scope of this invention.[23]

Pending claim 112 depends from claim 113, which depends from independent claim 111, and is directed to the "assembled bone implant of claim 113, wherein said first cortical bone portion and said second cortical bone portion each have a D shape."[24] Support for claim 112 can be found throughout the specification of the application as filed, including at the same passages noted above for claim 111, and as noted below for claim 113. Specific support for the elements of the first cortical bone portion and said second cortical bone portion each having a D shape can be found throughout the specification of the application as filed, including at p. 2, lines 17-25

[23] Exhibit 1, at p. 18, line 18 to p. 19, line 10, Evidence Appendix. (Emphasis added).

[24] Claim 112, Claims Appendix.

("substantially "D"-shaped cortical bone implant"); at p. 3, lines 3-7 ("the implant is derived from allograft or autograft cortical bone sources, is machined to form a substantially "D"-or other appropriately shaped implant"); at p. 4, lines 14-15 ("According to this invention, a substantially "D"-shaped cortical bone implant for cervical Smith-Robinson fusions is produced"); at p. 8, lines 13-26 ("It will be recognized that, based on the instant disclosure, a substantially "D"-shaped external profile of the implant may be machined by a variety of means"); at p. 10, lines 3-9 ("to provide a substantially "D"-shaped cortical bone implant with flat upper and lower surfaces"); at original claims 28 and 33; and at the Abstract at p. 37, lines 3-8 ("The implant is derived from allograft or autograft cortical bone sources, is machined to form a symmetrically or asymmetrically shaped (e.g. a substantially "D"-shaped) implant").[25]

Pending claim 113 depends from independent claim 111, and is directed to the "assembled bone implant of claim 111, wherein said first cortical bone portion is stacked over said second cortical bone portion."[26] Support for claim 113 can be found throughout the specification of the application as filed, including at the same passages noted above for claim 111. Specific support for the elements of the first cortical bone portion being stacked over said second cortical bone portion can be found throughout the specification of the application as filed, including at p. 3, line 23 "FIG. 7 provides a view of a stacked embodiment of the implant"); at p. 3, line 27 to p. 4, line 3 "FIG. 9 provides a view of a stacked embodiment of the implant"); at p. 6, lines 6-11 ("implants of this invention are produced and then stacked to provide a unitary implant"); at p. 6, lines 11-15 ("Alternatively, the stacked implants may be retained in a unitary association by means of a plug of cancellous bone"); at p. 18, lines 18-20 ("to allow stacking thereof to achieve implants of various heights"); at p. 18, lines 22-25 ("two implant blanks of known height are selected such that a unitary implant composed of both starting implants can be produced of a new desired height"); and at original claims 25 and 49.[27]

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[25] Exhibit 1, Evidence Appendix.

[26] Claim 113, Claims Appendix.

[27] Exhibit 1, Evidence Appendix.

Pending claim 114 depends from claim 112, and is directed to the "assembled implant of claim 112, wherein said retention pin is selected from the group consisting of cortical bone, a bioabsorbable synthetic polymer and titanium."[28] Support for claim 114 can be found throughout the specification of the application as filed, including at the same passages noted above for claims 111-113. Specific support for the elements of the retention pin being selected from the group consisting of cortical bone, a bioabsorbable synthetic polymer and titanium can be found throughout the specification of the application as filed, including at p. 6, lines 6-11 ("retention pins made from any desirable material, including cortical bone, bioabsorbable synthetic polymer, titanium or other metallic retention pins"); and at p. 18, line 27 to p. 19, line 2 ("Pins, composed of cortical bone, resorbable but strong biocompatible synthetic material, or metallic pins").[29]

Pending claim 115 depends from claim 114 and is a subset thereof. Claim 115 is directed to the "assembled implant of claim 114, wherein said retention pin is cortical bone."[30] Claim 115 is supported by the same disclosures in the specification that support claim 114, as described above.

Pending claim 116 depends from claim 111, and is directed to the "assembled implant of claim 111, wherein said first cortical bone portion is a mirror image of said second cortical bone portion."[31] Support for claim 114 can be found throughout the specification of the application as filed, including at the same passages noted above for claim 111. Specific support for the elements of the first cortical bone portion being a mirror image of said second cortical bone portion can be found throughout the specification of the application as filed, including at p. 3, lines 24-26 ("juxtaposition of mirror image halves of the implant"); and at original claims 10, 16, 26 and 50.[32]

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[28] Claim 113, Claims Appendix.

[29] Exhibit 1, Evidence Appendix.

[30] Claim 115, Claims Appendix.

[31] Claim 116, Claims Appendix.

[32] Exhibit 1, Evidence Appendix.

Pending claim 117 depends from claim 112, and is directed to the "assembled implant of claim 112, wherein the implant has a beveled edge of defined radius."[33] Support for claim 114 can be found throughout the specification of the application as filed, including at the same passages noted above for claims 111-112. Specific support for the elements of the implant having a beveled edge of defined radius can be found throughout the specification of the application as filed, including at p. 10, lines 18-19 ("a beveled edge of defined radius is preferably machined into three faces of the implant"); at Figures 1C and 1D, and at the discussion of Figures 1C and 1D at p. 11, lines 5-10 ("In addition, a "radius" or bevel 115 is shown on the two side and posterior edges of the implant").[34]

Pending claim 118 depends from claim 115, and is directed to the "assembled implant of claim 115, wherein said first cortical bone portion and said second cortical bone portion are in a stacked position relative to one another."[35] Claim 118 is supported by the same disclosures in the specification that support claim 113, as described above.

Pending claim 120 depends from claim 112, and is directed to the "assembled implant of claim 112, wherein said first cortical bone portion and said second cortical bone portion are allograft bone."[36] Support for claim 120 can be found throughout the specification of the application as filed, including at the same passages noted above for claims 111-112. Specific support for the elements of the first cortical bone portion and the second cortical bone portion being allograft bone can be found throughout the specification of the application as filed, including at p. 3, lines 3-7 ("the implant is derived from allograft or autograft cortical bone sources"); at p. 4, lines 23-25 ("The bone source... is preferably, allograft bone"); and at the Abstract, at p. 37, lines 3-8 ("The implant is derived from allograft or autograft cortical bone sources").

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[33] Claim 117, Claims Appendix.

[34] Exhibit 1, Evidence Appendix.

[35] Claim 118, Claims Appendix.

[36] Claim 120, Evidence Appendix.

Pending claim 121 depends from claim 112, and is directed to the "assembled implant of claim 112, sized and shaped in the form of a cervical implant."[37] Support for claim 121 can be found throughout the specification of the application as filed, including at the same passages noted above for claims 111-112. Specific support for the elements of the implant being sized and shaped in the form of a cervical implant can be found throughout the specification of the application as filed, including at p. 1, lines 18-21 ("This invention relates to a cortical bone implant for use in cervical Smith-Robinson vertebral fusion procedures"); at p. 2, lines 17-25 ("The present invention provides a new cortical bone implant for use in achieving anterior cervical fusions when implanted according to the Smith-Robinson procedure"); at p. 3, lines 3-7 ("An implant composed substantially of cortical bone is provided for use in cervical Smith-Robinson vertebral fusion procedures"); at p. 4, lines 14-15 ("a substantially "D"-shaped cortical bone implant for cervical Smith-Robinson fusions is produced"); and at the Abstract at p. 37, lines 3-8 ("An implant composed substantially of cortical bone is provided for use in cervical Smith-Robinson vertebral fusion procedures. The implant is... inserted into the space between adjacent cervical vertebrae to provide support and induce fusion of the adjacent vertebrae").[38]

Pending claim 122 depends from claim 112, and is directed to the "assembled implant of claim 112, having a height between 7 and 14 mm."[39] Support for claim 122 can be found throughout the specification of the application as filed, including at the same passages noted above for claims 111-112. Specific support for the elements of the implant having a height between 7mm and 14 mm can be found throughout the specification of the application as filed, including at p. 5, lines 24-26 ("final implant heights from about 7 mm to about 14 mm may be produced"); at p. 18, lines 22-25 ("a unitary implant composed of both starting implants can be produced of a new desired height (e.g. a 6 mm high implant may be stacked with a 7 mm high implant to produce a 13 mm implant)"); and at p. 24, lines 3-5 ("implants are provided having a

[37] Claim 121, Claims Appendix.

[38] Exhibit 1, Evidence Appendix.

[39] Claim 122, Claims Appendix.

height of between about 7 and 14 mm, a length of between about 11 and 14 mm and a width of between about 11 and 14 mm").[40]

Pending claim 123 depends on claim 111, and is directed to the "assembled implant of claim 111, wherein said one or more retention pins comprise a cancellous bone portion."[41] Support for claim 123 can be found throughout the specification of the application as filed, including at the same passages noted above for claim 111. Specific support for the elements of the or more retention pins comprising a cancellous bone portion can be found, for example, at p. 3, line 27 to p. 4, line 3:

> a stacked embodiment of the implant of this invention wherein the stacked constituents thereof are retained in registered relationship by press-fitting or otherwise bringing more than one implant into contact with each other and having <u>a cancellous plug</u> or other biocompatible material located in the central canal of each stacked implant, <u>thereby acting as a retention pin</u>.[42]

Additional support for the elements of the or more retention pins comprising a cancellous bone portion can be found throughout the specification of the application as filed, including at p. 6, lines 11-15 ("stacked implants may be retained in a unitary association by means of a plug of cancellous bone"); at Figure 9 and the discussion thereof at p. 19, lines 12-17 ("By press-fitting the two implants together using an appropriately shaped cancellous plug 905"); and at p. 22, lines 19-20 ("a cancellous plug").[43]

Pending claim 124 depends from claim 123, and is directed to the "assembled implant of claim 123, wherein said cancellous bone portion is treated with a bone morphogenetic protein (BMP)."[44] Support for claim 124 can be found throughout the specification of the application as filed, including at the same passages noted above for claim 123. Specific support for the elements of the cancellous bone portion being treated with a bone morphogenetic protein can be

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[40] Exhibit 1, Evidence Appendix.

[41] Claim 123, Claims Appendix.

[42] Exhibit 1, Evidence Appendix. (Emphasis added).

[43] Exhibit 1, Evidence Appendix.

[44] Claim 124, Claims Appendix.

found throughout the specification of the application as filed, including at Figure 9 and the discussion thereof at p. 19, lines 12-17:

> By press-fitting the two implants together using an appropriately shaped <u>cancellous plug</u> 905 or a plug made from another biocompatible material, including but not limited to hydroxyapatite, cortical bone, synthetic materials, ceramic, <u>optionally treated with growth factors such as bone morphogenetic protein</u> and the like, the two implants 901 and 902 are retained in registered juxtaposition to form the implant 900.[45]

Pending claim 125 depends from claim 112, and is directed to the "assembled implant of claim 112, wherein said implant has two opposing surfaces that are inscribed with teeth."[46] Support for claim 125 can be found throughout the specification of the application as filed, including at the same passages noted above for claims 111-112. Specific support for the elements of the implant having two opposing surfaces that are inscribed with teeth can be found throughout the specification of the application as filed, including at p. 3, lines 19-20 ("an apparatus for inscribing retention teeth in the upper surface, lower surface or both upper and lower surfaces of the implant"); at p. 10, lines 3-9 ("an external feature may be machined into the upper and lower surfaces.... This may be achieved by... ribbing or teeth into the upper, lower, or both surfaces of the implant"); at Figure 1D and the discussion thereof at p. 11, lines 5-10 ("the external feature 120 has the side profile of a set of teeth"); at Figure 5 and the discussion thereof at p. 16, lines 24-26 ("blades 502 for use in a broach assembly 500 for inscribing teeth into the top 110, bottom 111 or both surfaces of the implant"); at Figure 7 and the discussion thereof at p. 19, lines 4-6 ("In this view, the adjacent surfaces 710A and 710B have not been inscribed with teeth, while the surfaces 711A and 711B have been so inscribed"); and at original claims 51 and 52.[47]

Pending independent claim 126 is directed to "A D-shaped assembled bone implant for implantation into a patient comprising: a first cortical bone portion having a D shape; and a

[45] Exhibit 1, Evidence Appendix.

[46] Claim 125, Claims Appendix.

[47] Exhibit 1, Evidence Appendix.

second cortical bone portion having a D-shape; said first cortical bone portion and said second cortical bone portion being superimposed to form D-shaped implant having the combined thickness of said first cortical bone portion and said second cortical bone portion, said D-shaped implant having a through-hole sized and positioned for receiving a retention pin for retaining said first cortical bone portion to said second cortical bone portion in stacked formation."[48] Support for claim 126 can be found throughout the specification of the application as filed, including at the same passages noted above for claims 111-113. For example, Figures 7A and 7B illustrate an implant including each of the elements recited in claim 126, and the discussion of these Figures on pp. 18-19 of the specification of the application as filed describes how the first cortical bone portion and the second cortical bone portion are retained in stacked formation by through holes that receive retention pins.[49]

Pending claim 127 depends from claim 126, and is directed to the "assembled implant of claim 126, wherein said retention pin is a cortical bone pin."[50] Claim 127 is supported by the same disclosures in the specification that support claims 114-115, as described above.

Pending claim 128 depends from claim 126, and is directed to the "assembled implant of claim 126, wherein said retention pin is a cancellous bone portion is treated with a bone morphogenetic protein."[51] Claim 128 is supported by the same disclosures in the specification that support claim 124, as described above.

Pending independent claim 129 is directed to "an assembled bone implant suitable for implantation into a patient comprising: a first cortical bone portion of allograft bone; a second cortical bone portion of allograft bone; said first cortical bone portion and said second cortical bone portion having one or more through holes sized and aligned for receiving one or more retention pins for connecting said first cortical bone portion to said second cortical bone portion; and one or more retention pins of appropriate diameter for connecting said first cortical bone

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[48] Claim 126, Claims Appendix.

[49] See Exhibit 1, at Figures 7A and 7B, and at p. 18, line 18 to p. 19, line 7, Evidence Appendix.

[50] Claim 127, Claims Appendix.

[51] Claim 128, Claims Appendix.

portion to said second cortical bone portion and forming said assembled bone implant outside the body of a patient as a unitary body suitable for implantation into a patient."[52] Claim 129 is supported by the same disclosures in the specification that support claims 111 and 120, as described above.

Claims 130-136 ultimately depend from claim 129, and recite the same limitations as claims 112-118, respectively. Claims 130-136 are supported by the same disclosures in the specification that support claims 111-118, as described above.

In view of the foregoing discussion, the invention as claimed is fully supported by the application as originally filed.

VI. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

1. Whether the Examiner erred in rejecting claims 111-118, 120-123, and 129-136 under 35 U.S.C. §102(b) in view of Fred H. Albee, "Bone Surgery With Machine Tools," Scientific American, Vol. 154, No. 4, pp. 178-181 (1936),[53] (hereinafter the "Albee" reference) where the cited reference does not disclose each and every element of the rejected claims.

2. Whether the Examiner erred in rejecting claims 111-118 and 120-136 under 35 U.S.C. §103(a) over U.S. Pat. No. 5,989,289 (hereinafter the "Coates" reference) [54] in view of European Patent Application No. 0517030 (hereinafter the "Siebels" reference) [55] where the cited references provide no basis to combine the reference teachings, nor a reasonable expectation of success with respect to making such a combination of the reference teachings, and where the cited references do not disclose each and every element of the rejected claims.

3. Whether the Examiner erred in rejecting claims 111-118 and 120-136 under 35 U.S.C. §103(a) over U.S. Pat. No. 5,192,327 (hereinafter the "Brantigan" reference)[56] in view of

[52] Claim 129, Claims Appendix.

[53] Exhibit 17, Evidence Appendix.

[54] Exhibit 18, Evidence Appendix.

[55] Exhibit 19, Evidence Appendix. (English translation attached.)

[56] Exhibit 20, Evidence Appendix.

the Coates reference where the cited references provide no basis to combine the reference teachings, nor a reasonable expectation of success with respect to making such a combination of the reference teachings, and where the cited references do not disclose each and every element of the rejected claims.

VII. ARGUMENT

A. The Albee Reference Does Not Anticipate the Pending Claims, and the Rejection Under 35 U.S.C. §102(b) Should Therefore Be Withdrawn

The Examiner erred in rejecting claims 111-118, 120-123, and 129-136 under 35 U.S.C. §102(b) in view of Fred H. Albee, "Bone Surgery With Machine Tools," Scientific American, Vol. 154, No. 4, pp. 178-181 (1936),[57] (hereinafter the "Albee" reference) because the cited reference does not disclose each and every element of the rejected claims.

With regard to the anticipation rejections, MPEP §2131 states, "[a] claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference."[58] MPEP §2131 also states, "[t]he identical invention must be shown in as complete detail as is contained in the... claim."[59] In contrast, where claimed elements are not described in the cited reference, there is no anticipation.[60]

The current rejection under 35 U.S.C. §102(b) in view of the Albee reference is based solely upon the Figures, particularly upon Figure 3 and various subparts thereof,[61] without any

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[57] Exhibit 17, Evidence Appendix.

[58] MPEP §2131, quoting Verdegaal Bros. v. Union Oil Co. of California, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed.Cir. 1987).

[59] MPEP §2131, quoting Richardson v. Suzuki Motor Co., 868 F.2d 1226, 1236, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989).

[60] See, e.g., Richardson v. Suzuki Motor Co., 868 F.2d 1226, 1236, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989) (Jury verdict of no anticipation affirmed where references did not disclose elements as claimed in patent, such as a bell crank that was pivotally mounted to the motorcycle frame but not at a mid-point as claimed); Merck & Co., Inc. v. Teva Pharms. USA, Inc., 347 F.3d 1367, 1372, 68 U.S.P.Q. 2d 1857, 1861 (Fed. Cir. 2003) (No anticipation where there was no suggestion of the claimed therapeutic uses in the cited reference, and the reference did not identify the particular compound of the claim as having superior bone reabsorption properties).

[61] Exhibit 15, at pp. 2-3 and 6-7, Evidence Appendix.

consideration being given to the textual descriptions of the Albee implants. The interpretation of the figures in the Albee reference in this manner, which disregards the context and description thereof, is improper. When the Albee reference is read as a whole, as required by MPEP §2141.02,[62] and the Figures are understood based upon the description thereof in the Albee reference, it becomes evident that the Albee reference does not disclose each and every element as set forth in any of the currently pending claims, and therefore none of the currently pending claims is anticipated by the Albee reference.

1. The Albee Reference Does Not Anticipate Pending Claim 111

Pending Independent claim 111 is directed to "[a]n assembled bone implant suitable for implantation into a patient comprising: a first cortical bone portion; a second cortical bone portion; said first cortical bone portion and said second cortical bone portion having one or more circular through holes sized and positioned for receiving one or more retention pins for connecting said first cortical bone portion to said second cortical bone portion; and one or more retention pins of appropriate diameter for fitting said through holes and connecting said first cortical bone portion to said second cortical bone portion and forming said assembled bone implant as a unitary body outside of said patient, said assembled bone implant being suitable for implantation into said patient."[63]

As an initial matter, the Albee reference does not disclose an "assembled bone implant suitable for implantation into a patient comprising: a first cortical bone portion; and a second cortical bone portion," as required by pending claim 111. The assembled bone implant of pending claim 111, as claimed, exists as a "unitary body outside of a patient," and is suitable for implantation into the patient. In contrast, the implants disclosed in the Albee reference are peg grafts that are a single piece of living bone, rather than being multiple pieces of cortical bone that are assembled to form an implant.

[62] MPEP §2141.02 ("A prior art reference must be considered in its entirety, i.e., as a whole, including portions that would lead away from the claimed invention")(emphasis in original).

[63] Claim 111, Claims Appendix.

For example, the Albee reference states that a "graft may be shaped into any sized peg desired, by means of the lathe attachment. A close fit is assured by selecting the appropriate sized drill (Figure 6, O, P) when making the hole for such peg grafts."[64] The caption of Figure 6 describes the implants as being a "dowel" or an "inlay" that is inserted into the patient's body:

> Figure 6: A is the twin saw. Speed 3000 r.p.m. B is a miller for pointing the end of a bone dowel, as in C. D is a dowel after rounding in E, and F is a die for threading s bone screw like F'. Dowels and screws like these are made on the spot from bone removed from the patient's own body and inserted elsewhere in it – all in one minute by the clock. I is a jaw bone, with an **inlay** taken from the shin. Not only does the living bone unite with the jaw bone, but it grows, filling in the whole gap."[65]

An inlay graft is also illustrated in Figure 5 of the Albee reference, and is described in the caption as being a "long, slender, square piece of shin bone which has been set across as an inlay."[66] The Albee reference further describes the grafts disclosed therein as being "a graft of the general size of a lead pencil, and of any shaped cross section."[67] The Albee reference describes the implants disclosed therein as being single, individual pieces of bone that are removed from the patient, shaped using machine tools in the operating room, and then implanted elsewhere in the patient.

Albee thus discloses shaping a single piece of the patient's own (autograft) bone to fit between two opposing segments of the patient's living in vivo bone to bridge a size gap or hold the two opposing living segments in appropriate juxtaposition. The resulting assembled structure is not an "assembled implant" as recited in claim 111, it is a reconstructed area within a patient. The assembly of a patient's bones in combination with a graft as disclosed in Albee exists only as an *in vivo* construct, and is not an "assembled implant" as recited in pending claim 111, because that would require removing the patients' own bones and the interconnecting piece so that they exist *in vitro* as an assembled implant. Thus, at no time does the Albee reference

[64] Exhibit 17, at p. 181, Evidence Appendix. (Emphasis added).

[65] Exhibit 17, at p. 181 (Figure 6), Evidence Appendix. (Emphasis added).

[66] Exhibit 17, at p. 181 (Figure 5), Evidence Appendix.

[67] Exhibit 17, at p. 180, Evidence Appendix.

provide any discussion in which a first piece of bone and a second piece of bone are assembled into a unitary implant outside a patient's body and then implanted into the patient.

The Examiner has improperly relied upon two separate conclusory presumptions to maintain the pending rejection under 35 U.S.C. §102(b) in view of Albee. One presumption asserted by the Examiner is that "the assembled bone portions of Albee are capable of being used as donor tissue and implanted into a second patient which fulfills all functional language."[68] The other presumption is that "in situations of multiple breaks, it is conceivable that the bone portions are connected together outside of the body and than [sic] placed back, such as skull fractures."[69] These presumptions improperly read elements into the Albee reference that are not disclosed therein, and thus disregard the requirements of MPEP §2131 that each and every element as set forth in the claim must be found in a single prior art reference and that the elements must be arranged as required by the claim. Conclusory presumptions regarding how the teachings of a reference might by modified are improper with respect to obviousness rejections under 35 U.S.C. §103,[70] and certainly have no place in an anticipation rejection under 35 U.S.C. §102(b). The pending rejection under 35 U.S.C. §102(b) should therefore be withdrawn.

The presumption that "the assembled bone portions of Albee are capable of being used as donor tissue and implanted into a second patient which fulfills all functional language"[71] is particularly troubling because it directly contradicts the teachings of Albee. As discussed above, the Albee reference does not disclose "assembled bone portions" that form an implant. Any "assembled bone portions" shown in Albee include the implant of Albee in combination with the

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[68] Exhibit 15, at p. 2, Evidence Appendix.

[69] Exhibit 15, at p. 3, Evidence Appendix

[70] See, e.g., MPEP §2144.03(E) ("It is never appropriate to rely solely on common knowledge in the art without evidentiary support in the record as the principal evidence upon which a rejection was based"); MPEP §2143.01(I) (citing In re Lee, 277 F.3d 1338, 1342-44, 61 USPQ2d 1430, 1433-34 (Fed. Cir. 2002) regarding "the importance of relying on objective evidence and making specific factual findings with respect to the motivation to combine references"); MPEP §2143.01(IV) (citing Al-Site Corp. v. VSI Int'l Inc., 174 F.3d 1308, 50 USPQ2d 1161 (Fed. Cir. 1999) regarding that "[t]he level of skill in the art cannot be relied upon to provide the suggestion to combine references").

[71] Exhibit 15, at p. 2, Evidence Appendix.

bones of a patient as they would exist within a patient after a bone surgery. For example, sub-figures 1, 2a, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13 and 14 of Figure 3 in the Albee reference illustrate grafts implanted into the bones of patients.[72] These reconstructed areas consisting of an implant and the bones of the patient would not be removed from the patient and implanted into someone else. Further, the Albee reference itself teaches away from using the bone of one person as a graft for use in someone else. The Albee reference explicitly states that "it is desirable, if not essential, that the graft be autogenous; that is, come from the same individual."[73] The Albee reference also describes that "[d]owels and screws like these are made on the spot from bone removed from the patient's own body and inserted elsewhere in it – all in one minute by the clock."[74] The Editor's note within the Albee reference is also telling on this point in that it describes the article as relating to "the repair of damaged bones by means of living bone substance taken from the patient's own body."[75] The presumption that the grafts and bones of a patient could be used as implant in another patient flies in the face of the teachings of the Albee reference, and it was thus error for the Examiner to rely upon such a presumption in maintaining a rejection under 35 U.S.C. §102(b) in view of Albee.

As another matter, the Albee reference does not teach the element of "said first cortical bone portion and said second cortical bone portion having one or more circular through holes sized and positioned for receiving one or more retention pins for connecting said first cortical bone portion to said second cortical bone portion" as recited in claim 111.[76] Nor does the Albee reference disclose "one or more retention pins of appropriate diameter for fitting said through holes and connecting said first cortical bone portion to said second cortical bone portion and forming said assembled bone implant as a unitary body outside of said patient, said assembled

[72] Exhibit 17, at p. 179, Evidence Appendix.

[73] Exhibit 17, at p. 178, Evidence Appendix. (Emphasis added).

[74] Exhibit 17, at p. 181 (Figure 6 caption), Evidence Appendix. (Emphasis added).

[75] Exhibit 17, at p. 178 (Editor's note), Evidence Appendix. (Emphasis added).

[76] Claim 111, Claims Appendix.

bone implant being suitable for implantation into said patient," as recited in claim 111.[77] In concluding that the Albee reference discloses these elements, the Examiner has provided the following assertions:

> Note figure 3, sub-figures 1, 2a, 10, 11, 12, 15 which are interpreted as having through holes. Note the holes of sub-figures 11-12 extend through the front to back. The Examiner notes applicant's arguments regarding some of the figures are joinery techniques. However, Albee is teaching these can be used with bone. Referring to at least figure 3, sub-figure 15, it is unclear why applicant does not believe this is bone, however, it is clear to one having ordinary skill in the art interpreting the teachings of Albee, that this could be bone.[78]

These assertions are incorrect and improper on many levels. For example, figure 3 is captioned "The fine joinery element in bone surgery – a group of self-evident <u>analogies</u>."[79] The sub-figures of figure 3a illustrate various joints in wood, as well as analogous joints formed in the bones of patients by using the peg grafts disclosed in the Albee reference. The Albee reference is thus teaching the use of certain <u>types</u> of joints, and is not teaching that the wooden blocks illustrated in various sub-parts of figure 3 could actually be made of bone. Sub-figures 1, 2, 2a, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, illustrate the bone surgery examples.[80] In comparison, sub-figures 1a, 2b, 3a, 5a, 6a, 7a, 7b, 8a, 9a, 10a, 11a, 12a, 11b, 13a, 14a, and 15 serve as the joinery analogies, with sub-figure 14a being brace made of metal.[81] The illustration of these analogies between joinery and bone surgery, showing the differences between joints as known in wood as compared to joints as translated and adapted for use with bones, is evidence in itself that the illustrated joinery examples would not be construed by one of ordinary skill in the art as illustrating implants that could be made of bone. Thus, contrary to the assertions of the Examiner, sub-figures of figure 3 in the Albee reference that illustrate constructs of wood or metal do not anticipate the assembled bone implant recited in pending claim 111.

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[77] Claim 111, Claims Appendix.

[78] Exhibit 15, at p. 3, Evidence Appendix.

[79] Exhibit 17, at p. 179, Evidence Appendix. (Emphasis added).

[80] Exhibit 17, at p. 179 (figure 3, and caption of figure 3), Evidence Appendix.

[81] Exhibit 17, at p. 179 (figure 3, and caption of figure 3), Evidence Appendix.

Additionally, sub-parts 1 and 2a of figure 3 illustrate sutures tying the Albee implant to the broken bones of a patient,[82] and do not illustrate an assembled implant comprising two bone components having through holes where the bone portions have been connected by pins. The suture is illustrated by the knots on the left side of each illustrated suture. Figure 6, sub-figure I similarly illustrates a bone inlay secured to a jawbone by suture.[83] The fact that the implant illustrated in sub-figures 1 and 2a comprises neither multiple bone portions nor through holes is illustrated in sub-figures 1a and 2b, which illustrate the wooden analogies.[84] Sub-figure 1a shows bands around a joined wooden pole, and sub-figure 2b shows a single piece with no through holes.

Furthermore, sub-figures 10, 11 and 12 do not show an assembled implant comprising two cortical bone portions having circular through holes and being connected by pins. For example, sub-figures 11 and 12 illustrate keyed in tension members in a patient's patella. There is no basis in the Albee reference for the Examiner's assertion that the holes "extend through the front to back." [85] Even if the holes of those sub-figures could reasonably construed as being through holes, the holes are in the patient's bone and the implant is inserted into the holes. This is also the case with respect to sub-figure 10, which illustrates a circular peg graft inserted through one bone of a patient and into another bone. As the Albee reference describes, "The graft may be shaped into any sized peg desired, by means of the lathe attachment. A close fit is assured by selecting the appropriate sized drill (Figure 6, O, P) when <u>making the hole for such peg grafts</u>. It is important that the fit should be that of the accuracy of a glass-stopper in a bottle, and not that of a cork stopper, or a square peg in a round hole."[86] The holes illustrated in the Albee reference are not within components that make up the implant, and do not serve to connect

[82] Exhibit 17, at p. 179, Evidence Appendix.

[83] Exhibit 17, at p. 181, Evidence Appendix.

[84] Exhibit 17, at p. 179, Evidence Appendix.

[85] Exhibit 15, at p. 3, Evidence Appendix.

[86] Exhibit 17, at p. 181, Evidence Appendix. (Emphasis added).

components and thus form an assembled implant that is a unitary body outside the patient, as required by claim 111.

Because the Albee reference does not teach each and every element of claim 111, the Albee reference does not anticipate claim 111 and the pending rejection of this claim under 35 U.S.C. §102(b) should be withdrawn.

2. The Albee Reference Does Not Anticipate Pending Claims 120 and 129

Pending independent claim 129 is directed to "[a]n assembled bone implant suitable for implantation into a patient comprising: a first cortical bone portion of allograft bone; a second cortical bone portion of allograft bone; said first cortical bone portion and said second cortical bone portion having one or more through holes sized and aligned for receiving one or more retention pins for connecting said first cortical bone portion to said second cortical bone portion; and one or more retention pins of appropriate diameter for connecting said first cortical bone portion to said second cortical bone portion and forming said assembled bone implant outside the body of a patient as a unitary body suitable for implantation into a patient."[87] Claim 129 contains many elements that are the same as elements recited in claim 111, and also contains the additional limitation that each of the two one portions be allograft bone. Similarly, pending dependent claim 120 is directed to "[t]he assembled implant of claim 112, wherein said first cortical bone portion and said second cortical bone portion are allograft bone."[88] Claim 120 depends from claim 112, which depends from claim 113, which depends from claim 111. Claim 120 thus contains the limitations of claims 111, 112, and 113. The Albee reference does not anticipate pending claims 120 and 129 for all of the reasons discussed with respect to claim 111. The Albee reference also does not anticipate claim 120 for all of the reasons discussed below with respect to claims 112, and 113.

[87] Claim 129, Claims Appendix.

[88] Claim 120, Claims Appendix.

Additionally, pending claims 120 and 129 are not anticipated by the Albee reference because the Albee reference does not disclose an assembled implant comprising a first and second cortical bone portion that are allograft bone. Notably, the Examiner has not identified any portion of the Albee reference that is purported to teach the limitation added in dependent claim 120.[89] Instead, the Examiner has made the conclusory presumption that "the assembled bone portions of Albee are capable of being used as donor tissue and implanted into a second patient which fulfills all functional language."[90] As discussed above, however, this presumption flies in the face of the teachings of the Albee reference, which disclose only the use of autograft bone.[91] The Albee reference explicitly states that "it is <u>desirable, if not essential</u>, that the graft be <u>autogenous; that is, come from the same individual</u>."[92] The Albee reference also describes that "[d]owels and screws like these are made on the spot from bone removed <u>from the patient's own body</u> and inserted elsewhere in it – all in one minute by the clock."[93] The Editor's note within the Albee reference describes the article as relating to "the repair of damaged bones by means of living bone substance <u>taken from the patient's own body</u>."[94] The Albee reference thus relates only to autograft bone, and does not teach or suggest the use of allograft bone. Because the Albee reference does not teach each and every element of claims 120 and 129, the Albee reference does not anticipate claims 120 and 129, and the pending rejection of this claim under 35 U.S.C. §102(b) should be withdrawn.

3. The Albee Reference Does Not Anticipate Pending Claim 112

Pending claim 112 depends from claim 113, which depends from claim 111, and is directed to "[t]he assembled bone implant of claim 113, wherein said first cortical bone portion

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[89] <u>See</u> Exhibits 11, 13 and 15, Evidence Appendix.

[90] Exhibit 15, at p. 2, Evidence Appendix.

[91] <u>See</u> Exhibit 17, at p.

[92] Exhibit 17, at p. 178, Evidence Appendix. (Emphasis added).

[93] Exhibit 17, at p. 181 (Figure 6 caption), Evidence Appendix. (Emphasis added).

[94] Exhibit 17, at p. 178 (Editor's note), Evidence Appendix. (Emphasis added).

and said second cortical bone portion each have a D shape."[95] The Albee reference does not anticipate pending claim 112 for all of the reasons discussed with respect to claim 111 above, and with respect to claim 113 below. Additionally, pending claim 112 is not anticipated by the Albee reference because the Albee reference does not disclose an assembled implant comprising a first cortical bone portion and a second cortical bone portion that each have a D shape.

The Examiner has misconstrued sub-figures 11 and 12 in figure 3 of the Albee reference in asserting that those sub-figures illustrate "first and second cortical bone portions [that] each have a D-shape having a through hole with [sic] receives the I shaped pin interpreted as having an appropriate diameter."[96] As the caption for figure 3 of the Albee reference notes, "Numbers 11 and 12 are keyed-in tension members in broken knee caps which will not join."[97] The bone interpreted by the Examiner as being two D-shaped cortical bone portions are thus the broken halves of a patient's knee cap, and are the bone into which the I shaped implant is inserted rather than being part of an implant as is required in pending claim 112. Additionally, the patella is not a cortical bone portion, but is primarily cancellous bone with only a thin cortical cap or surface layer. Because the Albee reference does not teach each and every element of claim 112, the Albee reference does not anticipate claim 112 and the pending rejection of this claim under 35 U.S.C. §102(b) should be withdrawn.

4. The Albee Reference Does Not Anticipate Pending Claim 130

Pending claim 130 depends from independent claim 129, and is directed to "[t]he assembled bone implant of claim 129, wherein said first cortical bone portion and said second cortical bone portion each have a D shape."[98] Claim 130 contains the same additional limitations as claim 112, but depends from a different independent claim, and therefore should be considered separately from claim 112. The Albee reference does not anticipate pending claim

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[95] Claim 112, Claims Appendix.

[96] Exhibit 13, at p. 4, Evidence Appendix.

[97] Exhibit 17, at p. 179 (Figure 3 caption), Evidence Appendix.

[98] Claim 130, Claims Appendix.

130 for all of the reasons discussed with respect to claim 129. Additionally, Albee reference does not anticipate pending claim 130 for all of the reasons discussed with respect to claim 112. Because the Albee reference does not teach each and every element of claim 130, the Albee reference does not anticipate claim 130 and the pending rejection of this claim under 35 U.S.C. §102(b) should be withdrawn.

5. The Albee Reference Does Not Anticipate Pending Claims 113 and 118.

Claim 113 is directed to "[t]he assembled bone implant of claim 111, wherein said first cortical bone portion is stacked over said second cortical bone portion."[99] Claim 118 is directed to "[t]he assembled implant of claim 115, wherein said first cortical bone portion and said second cortical bone portion are in a stacked position relative to one another."[100] Pending claims 113 and 118 ultimately depend from claim 111, and therefore the Albee reference does not anticipate pending claims 113 and 118 for all of the reasons discussed with respect to claim 111. Claim 118 is also not anticipated by the Albee reference for all the reasons discussed with respect to claims 112, 113, 114, and 115, which are all included in the dependency chain of claim 118.

Additionally, pending claims 113 and 118 are not anticipated by the Albee reference because the Albee reference does not disclose an assembled implant comprising a first cortical bone portion stacked over a second cortical bone portion, or an assembled implant where the first and second bone portions are otherwise in a stacked position relative to one another. The Examiner has not identified any portion of the Albee reference that is purported to teach the limitation added in dependent claims 113 or 118.[101] Furthermore, because the Albee reference is directed to peg grafts made from single pieces of bone, as discussed above, the Albee reference does not disclose assembled grafts comprising a first cortical bone portion and a second cortical bone portion that are stacked. Because the Albee reference does not teach each and every element

[99] Claim 113, Claims Appendix.

[100] Claim 118, Claims Appendix.

[101] See Exhibits 11, 13 and 15, Evidence Appendix.

of claims 113 and 118, the Albee reference does not anticipate claims 113 and 118, and the pending rejection of these claims under 35 U.S.C. §102(b) should be withdrawn.

6. The Albee Reference Does Not Anticipate Pending Claims 131 and 136.

Claim 131 is directed to "[t]he assembled bone implant of claim 129, wherein said first cortical bone portion is stacked over said second cortical bone portion."[102] Claim 136 is directed to "[t]he assembled implant of claim 133, wherein said first cortical bone portion and said second cortical bone portion are in a stacked position relative to one another."[103] Pending claims 131 and 136 each ultimately depend from independent claim 129, and are therefore not anticipated by the Albee reference for the same reasons addressed in the discussion of claim 129. Claim 136 is also not anticipated by the Albee reference for the reasons discussed with respect to claims 130, 132 and 133, which are in the dependency chain of claim 136. Additionally, because claims 131 and 136 contain the same limitations recited in claims 113 and 118, respectively, they are not anticipated by the Albee reference for the same reasons addressed in the discussion of claims 113 and 118. Claims 131 and 136 should be considered separately from claim 113 and 118 because they depend from different independent claims. Because the Albee reference does not teach each and every element of claims 131 and 136, the Albee reference does not anticipate claims 131 and 136, and the pending rejection of these claims under 35 U.S.C. §102(b) should be withdrawn.

7. The Albee Reference Does Not Anticipate Pending Claims 114 and 115

Claim 114 is directed to "[t]he assembled implant of claim 112, wherein said retention pin is selected from the group consisting of cortical bone, a bioabsorbable synthetic polymer and titanium."[104] Claim 115 is directed to "[t]he assembled implant of claim 114, wherein said

[102] Claim 131, Claims Appendix.

[103] Claim 136, Claims Appendix.

[104] Claim 114, Claims Appendix.

retention pin is cortical bone."[105] Pending claims 114 and 115 each ultimately depend from claim 111, and therefore the Albee reference does not anticipate pending claims 114 and 115 for all of the reasons discussed with respect to claim 111. Specifically, as discussed above, the peg grafts disclosed in the Albee reference are made from autograft bone and can implanted into a patient to connect pieces of broken bone within the patient. Pending claims 114 and 115 are not anticipated by the Albee reference because the Albee reference does not disclose a retention pin made from cortical bone, a bioabsorbable synthetic polymer, or titanium, that connects two cortical bone portions to form an assembled bone implant as a unitary body outside of a patient. Because the Albee reference does not teach each and every element of claims 114 and 115, the Albee reference does not anticipate claims 114 and 115 and the pending rejection of these claims under 35 U.S.C. §102(b) should be withdrawn.

8. The Albee Reference Does Not Anticipate Pending Claims 132 and 133

Claim 132 is directed to "[t]he assembled implant of claim 130, wherein said retention pin is selected from the group consisting of cortical bone, a bioabsorbable synthetic polymer and titanium."[106] Claim 133 is directed to "[t]he assembled implant of claim 132, wherein said retention pin is cortical bone."[107] Pending claims 132 and 133 each ultimately depend from independent claim 129, and are therefore not anticipated by the Albee reference for the same reasons addressed in the discussion of claim 129. Claims 132 and 133 are also not anticipated by the Albee reference for the reasons discussed with respect to claims 130, which is in the dependency chain of claims 132 and 133. Additionally, because claims 132 and 133 contain the same limitations recited in claims 114 and 115, respectively, they are not anticipated by the Albee reference for the same reasons addressed in the discussion of claims 114 and 115. Claims 132 and 133 should be considered separately from claim 114 and 115 because they depend from

[105] Claim 115, Claims Appendix.

[106] Claim 132, Claims Appendix.

[107] Claim 133, Claims Appendix.

different independent claims. Because the Albee reference does not teach each and every element of claims 132 and 133, the Albee reference does not anticipate claims 132 and 133, and the pending rejection of these claims under 35 U.S.C. §102(b) should be withdrawn.

9. The Albee Reference Does Not Anticipate Pending Claim 116

Pending claim 116 depends from claim 111, and is directed to "[t]he assembled implant of claim 111, wherein said first cortical bone portion is a mirror image of said second cortical bone portion."[108] The Albee reference does not anticipate pending claim 116 for all of the reasons discussed with respect to claim 111. Additionally, pending claim 116 is not anticipated by the Albee reference because the Albee reference does not disclose an assembled implant comprising a first cortical bone portion that is a mirror image of a second cortical bone portion. The only support identified by the Examiner in maintaining the rejection to claim 116 is sub-figure 15 of figure 3 in the Albee reference.[109] Sub-figure 15, however, is one of the joinery analogies illustrated in figure 3 of the Albee reference, showing a joint as used in the woodworking art, and is not an implant made of cortical bone components. Furthermore, as in each of the analogies presented in figure 3 of the Albee reference, the wooden blocks alleged by the Examiner to be mirror images in sub-figure 15 would translate into being the bones of the patient in the analogous bone surgery application. The patient's bones would not be components of the implant used to reconnect the bones. Also, the Albee reference does not discuss or illustrate any bone components of an implant as being mirror images of each other. The Albee reference therefore does not disclose assembled grafts comprising a first cortical bone portion and a second cortical bone portion that are mirror images. Because the Albee reference does not teach each and every element of claim 116, the Albee reference does not anticipate claim 116 and the pending rejection of this claim under 35 U.S.C. §102(b) should be withdrawn.

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[108] Claim 116, Claims Appendix.

[109] See, e.g., Exhibit 15, at p. 7, Evidence Appendix.

10. The Albee Reference Does Not Anticipate Pending Claim 134

Pending claim 134 is directed to "[t]he assembled implant of claim 133, wherein said first cortical bone portion is a mirror image of said second cortical bone portion."[110] Pending claim 134 ultimately depends from independent claim 129, and is therefore not anticipated by the Albee reference for the same reasons addressed in the discussion of claim 129. Claim 134 is also not anticipated by the Albee reference for the reasons discussed with respect to claims 130, 132, and 133, which are in the dependency chain of claim 134. Additionally, because claim 134 contains the same limitations recited in claim 116, it is not anticipated by the Albee reference for the same reasons addressed in the discussion of claim 116. Claim 134 should be considered separately from claim 116 because it depends from a different independent claim. Because the Albee reference does not teach each and every element of claim 134, the Albee reference does not anticipate claim 134, and the pending rejection of this claim under 35 U.S.C. §102(b) should be withdrawn.

11. The Albee Reference Does Not Anticipate Pending Claim 117

Pending claim 117 ultimately depends from claim 111, and is directed to "[t]he assembled implant of claim 112, wherein the implant has a beveled edge of defined radius."[111] The Albee reference does not anticipate pending claim 117 for all of the reasons discussed with respect to claim 111. Claim 117 is also not anticipated by the Albee reference for the reasons discussed with respect to claims 112 and 113, which are in the dependency chain of claim 117. Additionally, pending claim 117 is not anticipated by the Albee reference because the Albee reference does not disclose an assembled implant having a beveled edge of defined radius. The Examiner has not identified any portion of the Albee reference that is purported to teach the limitation added in dependent claim 117.[112] Furthermore, the Albee reference does not mention beveling the edge of any of the implants disclosed therein. Because the Albee reference does not

[110] Claim 134, Claims Appendix.

[111] Claim 117, Claims Appendix.

[112] See Exhibits 11, 13 and 15, Evidence Appendix.

teach each and every element of claim 117, the Albee reference does not anticipate claim 117 and the pending rejection of this claim under 35 U.S.C. §102(b) should be withdrawn.

12. The Albee Reference Does Not Anticipate Pending Claim 135

Pending claim 135 is directed to "[t]he assembled implant of claim 134, wherein the implant has a beveled edge of defined radius."[113] Pending claim 135 ultimately depends from independent claim 129, and is therefore not anticipated by the Albee reference for the same reasons addressed in the discussion of claim 129. Claim 135 is also not anticipated by the Albee reference for the reasons discussed with respect to claims 130, 132, 133, and 134, which are in the dependency chain of claim 134. Additionally, because claim 135 contains the same limitations recited in claim 117, it is not anticipated by the Albee reference for the same reasons addressed in the discussion of claim 117. Claim 135 should be considered separately from claim 117 because it depends from a different independent claim. Because the Albee reference does not teach each and every element of claim 135, the Albee reference does not anticipate claim 135, and the pending rejection of this claim under 35 U.S.C. §102(b) should be withdrawn.

13. The Albee Reference Does Not Anticipate Pending Claim 121

Claim 121 is directed to "[t]he assembled implant of claim 112, sized and shaped in the form of a cervical implant."[114] Claim 121 ultimately depends from claim 111, and the Albee reference does not anticipate pending claim 121 for all of the reasons discussed with respect to claim 111. Claim 121 is also not anticipated by the Albee reference for the reasons discussed with respect to claims 112 and 113, which are in the dependency chain of claim 121.

Additionally, pending claim 121 is not anticipated by the Albee reference because the Albee reference does not disclose an assembled implant sized and shaped in the form of a cervical implant. The Examiner has relied upon sub-figures 11 and 12 of figure 3 of the Albee

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[113] Claim 135, Claims Appendix.

[114] Claim 121, Claims Appendix.

reference as being "sized and shaped for [sic] in the form of a cervical implant."[115] This basis of rejection is improper because it directly contradicts the disclosure of the Albee reference with respect to sub-figures 11 and 12. The caption for figure 3 of the Albee reference states that "Numbers 11 and 12 are keyed-in tension members in broken knee caps which will not join."[116] Sub-figures 11 and 12 thus do not relate to cervical implants, and the Examiner committed a legal error in asserting that they do. Because the Albee reference does not teach each and every element of claim 121, the Albee reference does not anticipate claim 121 and the pending rejection of this claim under 35 U.S.C. §102(b) should be withdrawn.

14. The Albee Reference Does Not Anticipate Pending Claim 122

Pending claim 122 ultimately depends from claim 111, and is directed to "[t]he assembled implant of claim 112, having a height between 7 and 14 mm."[117] The Albee reference does not anticipate pending claim 122 for all of the reasons discussed with respect to claim 111. Claim 122 is also not anticipated by the Albee reference for the reasons discussed with respect to claims 112 and 113, which are in the dependency chain of claim 122. Notably, The Examiner has not identified any portion of the Albee reference that is purported to teach the limitation added in dependent claim 122.[118] Because the Albee reference does not teach each and every element of claim 117, the Albee reference does not anticipate claim 117 and the pending rejection of this claim under 35 U.S.C. §102(b) should be withdrawn.

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[115] See Exhibits 15, at p. 7, Evidence Appendix.

[116] Exhibit 17, at p. 179, Evidence Appendix. (Emphasis added).

[117] Claim 122, Claims Appendix.

[118] See Exhibits 11, 13 and 15, Evidence Appendix.

15. The Albee Reference Does Not Anticipate Pending Claim 123

Pending claim 123 depends from claim 111, and is directed to "[t]he assembled implant of claim 111, wherein said one or more retention pins comprise a cancellous bone portion."[119] The Albee reference does not anticipate pending claim 123 for all of the reasons discussed with respect to claim 111. Additionally, the Albee reference does not anticipate claim 123 because it does not disclose an assembled implant having one or more retention pins that comprise a cancellous bone portion. Notably, The Examiner has not identified any portion of the Albee reference that is purported to teach the limitation added in dependent claim 122.[120] Specifically, as discussed above, the peg grafts disclosed in the Albee reference are made from autograft bone and can implanted into a patient to connect pieces of broken bone within the patient. Pending claim 123 is not anticipated by the Albee reference because the Albee reference does not disclose a retention pin comprising a cancellous bone portion that connects two cortical bone portions to form an assembled bone implant as a unitary body outside of a patient. Because the Albee reference does not teach each and every element of claim 123, the Albee reference does not anticipate claim 123 and the pending rejection of this claim under 35 U.S.C. §102(b) should be withdrawn.

In view of the foregoing discussion, the Appellants respectfully submit that the Albee reference does not anticipate claims 111-118, 120-123 and 129-136. The Appellants therefore respectfully request that the pending rejection of these claims under 35 U.S.C. §102(b) be withdrawn.

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[119] Claim 123, Claims Appendix.

[120] See Exhibits 11, 13 and 15, Evidence Appendix.

B. The Coates Reference In View of the Siebels Reference Does Not Render the Claims 111-118 and 120-136 Obvious, and the Rejection Under 35 U.S.C. §103(a) Should Therefore Be Withdrawn

The Examiner erred in rejecting claims 111-118 and 120-136 under 35 U.S.C. §103(a) over the Coates[121] reference in view of the Siebels[122] reference where the cited references provides no basis to combine the reference teachings, nor a reasonable expectation of success with respect to making such a combination of the reference teachings, and where the cited references do not disclose each and every element of the rejected claims.

With respect to the present application, the Examiner made several errors in maintaining the pending obviousness rejection in over the Coates reference in light of the Siebels reference. For example, the Examiner has merely relied upon conclusory statements rather than establishing evidence of a basis to combine the cited references. Additionally, the pending obviousness rejection fails to consider the prior art references as a whole, including teachings within them that teach away from the combination that the rejection attempts to make. Further, the Examiner has not established any basis for concluding that one of ordinary skill in the art would have a reasonable expectation of success in combining the Siebels reference with the Coates reference.

1. Conclusory Statements are Insufficient to Establish a Basis For An Obviousness Determination Based Upon Combining The Coates Reference With The Siebels Reference

In the final Office Action, dated March 15, 2006, the Coates reference was cited as disclosing "a D-shaped cortical bone spinal implant."[123] The final Office Action, however, admitted that "Coates et al fails to teach said implant can comprise a first and second portion capable of being connected by a pin."[124] The final Office Action then asserted that "Siebels also teaches a spinal implant and teaches stacking portions 11 of the implant and connecting said

[121] Exhibit 18, Evidence Appendix.

[122] Exhibit 19, Evidence Appendix. (English translation attached.)

[123] Exhibit 15, at p. 7, Evidence Appendix.

[124] Exhibit 15, at p. 7, Evidence Appendix.

portions with pins 17."[125] The final Office Action then simply jumps to a conclusion of obviousness, stating that "[i]t would have been obvious to one having ordinary skill in the art to have utilized the teachings of Siebels to stack and connect individual implant portions with the D-shaped cortical bone implants of Coates wherein multiple portions could be stacked and connected by at least one pin in corresponding through holes to adjustably build the implant to a desired height (thickness) to best fill the disc space as desired by the surgeon."[126] The final Office Action thus oversimplifies both the Siebels reference and the Coates reference, and then simply makes a conslusory allegation of obviousness without articulating the specific understanding or principle that would motivate one of ordinary skill in the art to combine the cited prior art references. This oversimplification of the cited references, combined with the failure to provide an articulated motivation or suggestion to combine the two references with any reasonable expectation of success, resulted in an erroneous final rejection under 35 U.S.C. §103(a).

In making and maintaining a rejection based upon obviousness, "the examiner must show reasons that the skilled artisan, confronted with the same problems as the inventor and with no knowledge of the claimed invention, would select the elements from the cited prior art references for combination in the manner claimed."[127] Furthermore, "rejections on obviousness grounds cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness."[128]

The requirement for a reasoned basis upon which the combination of references is made is intended to ensure a proper analysis regarding obviousness, and avoid improper hindsight

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[125] Exhibit 15, at p. 7, Evidence Appendix.

[126] Exhibit 15, at p. 7, Evidence Appendix. See also Exhibit 15, at p. 4, Evidence Appendix ("It is the Examiner's position that it would have been obvious to one having ordinary skill in the art to have used the teaching of Siebels and have stacked the device of Coates to **adjustably** build the implant to a desired height (thickness) to best fill the disc space as desired by the surgeon")(emphasis in original).

[127] In re Rouffet, 149 F.3d 1350, 1357, 47 U.S.P.Q.2d 1453, 1457-58 (Federal Circuit 1998).

[128] In re Kahn, 441 F.3d 977, 988, 78 U.S.P.Q.2d 1329, (Federal Circuit 2006); See also Alza Corp. v. Mylan Labs, Inc., 464 F.3d 1286, 1291, 80 U.S.P.Q.2d 1001 (Federal Circuit 2006).

reasoning based upon simply picking and choosing elements from the prior art to arrive at the Appellants' claimed invention. As the Federal Circuit has explained in In re Rouffet:

> [A]n examiner may often find every element of a claimed invention in the prior art. If identification of each claimed element in the prior art were sufficient to negate patentability, very few patents would ever issue. Furthermore, rejecting patents solely by finding prior art corollaries for the claimed elements would permit an examiner to use the claimed invention itself as a blueprint for piecing together elements in the prior art to defeat the patentability of the claimed invention. Such an approach would be "an illogical and inappropriate process by which to determine patentability." Sensonics, Inc. v. Aerosonic Corp., 81 F.3d 1566, 1570, 38 U.S.P.Q.2D (BNA) 1551, 1554 (Fed. Cir. 1996).[129]

With respect to the present application, no basis for combining the cited references has been provided. Instead, improper hindsight reasoning has been applied by finding the individual elements of the Appellants' claims in separate references and then simply concluding that it would have been obvious to one of ordinary skill to combine those references. Clinging to an unproven possibility that the references could be combined to achieve the claimed invention without providing a reasoned rationale as to the basis for such a combination is an impermissible basis for an obviousness rejection, and the pending rejection under U.S.C. §103(a) based upon Coates in view of Siebels should be withdrawn.

2. The Cited references, Considered As A Whole, Do Not Provide A Basis To Combine The Siebels Reference With The Coates Reference To Arrive At The Subject Matter Of Claims 111-118 and 120-136

"It is impermissible within the framework of section 103 to pick and choose from any one reference only so much of it as will support a given position, to the exclusion of other parts necessary to the full appreciation of what such reference fairly suggests to one of ordinary skill in the art."[130] Instead, when prior art references are combined, the references must be considered in their entirety, "i.e., as a whole, including portions that would lead away from the claimed

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[129] In re Rouffet, 149 F.3d 1350, 1357, 47 U.S.P.Q.2d 1453, 1457-58 (Federal Circuit 1998).

[130] In re Wesslau, 147 USPQ 391, 393 (CCPA 1965)); see also Bausch & Lomb, Inc. v. Barnes-Hind Int'l, Inc., 230 USPQ 416, 420 (Fed. Cir. 1986).

invention."[131] Appellants respectfully submit that when the substance and teachings of the Siebels reference and the Coates reference are properly considered, it is clear that one of ordinary skill in the art would not combine the two references by using the teachings of Siebels to stack the implants of Coates because the two references relate to different approaches to making implants.

As an initial matter, the implants disclosed in the Coates reference differ from the assembled implants claimed in the present application in several respects. The Coates reference provides "spacers for engagement between vertebrae which are sized and configured to fill the space left after disectomy."[132] As described in Coates, "[t]he spacer 110 includes an anterior wall 111 having opposite ends 112, 113, a posterior wall 115 having opposite ends 116, 117 and two lateral walls 120, 121. Each of the lateral walls 120, 121 is connected between the opposite ends 112, 113, 116, 117 of the anterior 111 and posterior 115 walls to define a chamber 130. The walls are each composed of a bone composition, preferably cortical bone." [133] Furthermore, "The spacer 110 fits snugly with its flat surfaces against the posterior and lateral edges which prevents medial and lateral motion of the spacer 110 into vertebral arteries and nerves. This also advantageously reduces the time required for the surgery by eliminating the trial and error approach to achieving a good fit with bone grafts because the spacers can be provided in predetermined sizes."[134] The Coates reference thus describes spinal implants made from a single piece of cortical bone that are provided in predetermined sizes so that they can be selected to fill the space left after disectomy and provide a snug fit. In contrast to the claimed implants of the present application, the Coates reference does not describe assembled implants made from multiple pieces of cortical bone, nor does it describe connecting pieces using cortical bone pins.

The Examiner has asserted that "[i]t would have been obvious to one having ordinary skill in the art to have utilized the teachings of Siebels to stack and connect individual implant

[131] MPEP at § 2141.02. (Emphasis added.)

[132] Exhibit 18, at Col. 5, lns 8-10, Evidence Appendix. (Emphasis added).

[133] Exhibit 18, at Col. 5, ln 66 to Col. 6, ln 5, Evidence Appendix.

[134] Exhibit 18, at Col. 8, lns 60-67, Evidence Appendix. (Emphasis added).

portions with the D-shaped cortical bone implants of Coates wherein multiple portions could be stacked and connected by at least one pin in corresponding through holes to adjustably build the implant to a desired height (thickness) to best fill the disc space as desired by the surgeon."[135] Such a modification of the Coates reference, however, is inconsistent with the teachings of Coates. As discussed above, the Coates reference discloses single piece spacers that fill the space into which the spacer is implanted. Additionally, the Coates reference discusses some of the disadvantages and difficulties with respect to making implants from bone:

> Both allograft and autograft present additional difficulties. Graft alone may not provide the stability required to withstand spinal loads. Internal fixation can address this problem but presents its own disadvantages such as the need for more complex surgery as well as the disadvantages of metal fixation devices. Also, the surgeon is often required to repeatedly trim the graft material to obtain the correct size to fill and stabilize the disc space. This trial and error approach increases the length of time required for surgery. Furthermore, the graft material usually has a smooth surface which does not provide a good friction fit between the adjacent vertebrae. Migration and expulsion of the graft may cause neural and vascular injury, as well as collapse of the disc space. Even where such slippage does not occur, micromotion at the graft/fusion-site interface may disrupt the healing process that is required for fusion.
>
> Several attempts have been made to develop a bone graft substitute which avoids the disadvantages of metal implants and bone grafts while capturing advantages of both. In each case, developing an implant having the biomechanical properties of metal and the biological properties of bone without the disadvantages of either has been extremely difficult or impossible.[136]

By this statement, Coates teaches that as of its filing date (October 1995), cortical bone was not a traditional orthopedic implant material for spinal implants. Rather, it was considered "extremely difficult or impossible" to provide an implant that had the benefits of both bone and metal without their undesired properties. And, although the Coates reference goes on to describe

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[135] Exhibit 15, at p. 7, Evidence Appendix. See also Exhibit 15, at p. 4, Evidence Appendix ("It is the Examiner's position that it would have been obvious to one having ordinary skill in the art to have used the teaching of Siebels and have stacked the device of Coates to **adjustably** build the implant to a desired height (thickness) to best fill the disc space as desired by the surgeon.")

[136] Exhibit 18, at Col. 3, lns 17-40, Evidence Appendix. (Emphasis added).

its single piece bone implants as providing one solution to the difficulties associated with using bone implants, the Coates reference when read as a whole does not provide a basis for concluding that modifications to the structure of the Coates implants, such as those suggested by the Examiner to arrive at the subject matter of the currently pending claims, would result in a suitable implant.

Furthermore, the problem addressed by the Coates reference is the issue of developing implants made of bone that "avoid the disadvantages of metal implants."[137] In describing the benefits of the implants described therein, the Coates reference states:

> One benefit of the spacers of the present invention is that they combine the advantages of bone grafts with the advantages of metals, without the corresponding disadvantages. An additional benefit is that the invention provides a stable scaffold for bone ingrowth before fusion occurs. Still another benefit of this invention is that it allows the use of bone grafts without the need for metal cages or internal fixation, due to the compressive strength of the spacer and the means for resisting migration. [138]

Notably, the Coates reference does not discuss implants made from plastics, such as those described in the Siebels reference, or the advantages or disadvantages thereof as compared to either metal or bone implants, even though Coates does list plastics as being materials suitable to be used as carriers for osteogenic compositions to be packed in the chamber of the Coates implants.[139] The Coates reference thus does not provide any teaching with respect to the possibility or desirability of incorporating features from plastic implants into the implants disclosed in the Coates reference.

Likewise, the Siebels reference does not discuss implants made from bone, such as those described in the Coates reference, or the advantages or disadvantages thereof as compared to the plastic implants disclosed in the Siebels reference. The Siebels reference thus does not provide any teaching with respect to the possibility or desirability of utilizing the features from the implants disclosed therein to modify implants such as those described in the Coates reference.

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[137] Id. at Col. 2, lns 50-51.

[138] Exhibit 18, at Col. 4, lns 8-16, Evidence Appendix.

[139] Exhibit 18, at Col. 7, lns 23-25, Evidence Appendix.

For example, the Siebels reference describes the basis of the invention described therein in the following manner:

> Therefore, the objective to develop an implant of the kind mentioned at the outset, which can rapidly be implanted and which – from the standpoint of manufacturing engineering – can also easily be manufactured for a multiplicity of overall dimensions, forms the basis of the [proposed] invention.[140]

Ease of manufacturing and ease of implantation are thus aspects of the basis for the Siebels invention, and serve as the solutions for the nature of the problem addressed by Siebels. The structural elements and physical characteristics of the implants disclosed in Siebels are based upon the manner in which the implants are manufactured and the materials used.

With respect to the structural elements and physical characteristics of the implants disclosed in Siebels, the Siebels reference describes that:

> The disk-shaped implant is preferably made of fiber-reinforced plastic [FRP]. In accordance with a preferred embodiment of the invention, in order to produce a single-piece implant, the disk is cut out of a hollow strand, which consists of a multiple number of braiding layers [plaiting layers]. The braiding layers, are wound up one after another on a correspondingly shaped mandrel [arbor], preferably on a mandrel, having a rectangular cross-section and rounded corners, directly in a braiding machine. The disks are cut off with the desired height, which can vary over the disk. Implants of this kind are characterized in that they can be manufactured in an extraordinarily easy way, in which the fiber orientation equally imparts an optimal rigidity and strength to the implant.[141]

As another example, the Siebels reference particularly describes its stacked embodiments with reference to the manufacturing techniques:

> In accordance with an embodiment of the invention, the disks have aligned boreholes, into which anchoring pins or studs can be inserted. In that embodiment, the disks are radially connected to one another, and also in such a way that they resist the torsional stress [i.e. possess torsional strength], and cannot rotate. Moreover, from a manufacturing engineering standpoint, the manufacturing of the disks in very easy.[142]

[140] Exhibit 19, English translation at p. 2, Evidence Appendix. (Emphasis added).

[141] Exhibit 19, English translation at pp. 3-4, Evidence Appendix. (Emphasis added).

[142] Exhibit 19, English translation at p. 5, Evidence Appendix. (Emphasis added).

The Siebels reference then proceeds to describe the easy manufacturing techniques in the following manner:

> Known winding techniques may be used for series-manufacturing of the implant elements. For example, the annular disks ["washers"] can be made with the help of a braiding machine, which is additionally outfitted with unidirectional fibers (UD). By means of bar-shaped mandrel, which is pulled through the braid eyelet, around which there are laid UD-fibers and braiding, a bonded-fiber tube is generated in a single run, from which the annular disks are afterwards cut off. The bar-shaped mandrel is preferably of PTFE (polytetrafluoroethylene), which is also used as mold release agent. At the same time, the bar-shaped mandrel can have a polygonal cross-sectional area, or grooves all over the length, and/or elevations, as a result of which the inner-jacket geometry, required for the torsionally-resistant anchoring, can directly be formed in the bonded-fiber tubes, respectively in the annular disks, over the course of their manufacturing.
>
> Also, winding methods using fibers or fiber-woven fabrics allow a manufacturing process, which is simple from the standpoint of manufacturing engineering, and suitable for series-manufacturing. Unified struts for the individual disks and the disk packages [packings] can be designed.[143]

The structure and shape of the disks described by Siebels are thus dictated by the braided or wound strands from which they are cut, and even the strength and rigidity of the disks is a result of the oriented fibers that result from the manufacturing techniques. The manufacturing methods taught in the Siebels reference that achieve the described advantages may be suitable for use with the plastics described in Siebels, but they could not be performed on cortical bone, and there is no teaching within the Siebels reference regarding whether the implants disclosed therein would possess the necessary physical properties (e.g., strength, rigidity, resistance to torsional stress) if applied to implants made from bone, such as those disclosed in the Coates reference. There is no basis in the Siebels reference for concluding that the disclosed manufacturing techniques could be altered or disregarded in making the disks taught therein

The pending rejection under 35 U.S.C. §103(a) improperly disregards the teachings of Siebels with respect to manufacturing. For example, the final Office Action stats that the combination of Coates and Siebels "has nothing to do with how easy or difficult it is to build

[143] Exhibit 19, English translation at pp. 6-7, Evidence Appendix. (Emphasis added).

either implant of Siebels and Coates"[144] and that "the fact that Siebels recognized another advantage of their invention does not take away from the teaching and advantage of multiple portions stacked and connected by at least one pin in corresponding through holes to adjustably build the implant to a desired height (thickness) to best fill the disc space as desired by the surgeon."[145] These assertions illustrate that the pending rejection under 35 U.S.C. §103(a) is based upon an improper picking and choosing of elements from Siebels to support the asserted combination, without proper consideration of the reference in its entirety to obtain a full appreciation of what the reference fairly suggests to one of ordinary skill in the art.[146]

In reading the Siebels reference, one of ordinary skill would be led towards the ease of manufacturing obtained by using the plastics and manufacturing methods described in Siebels, as well as the desirable physical properties provided by such manufacturing methods and materials. One of ordinary skill in the art would therefore be led in a divergent direction from developing different manufacturing techniques to allow the use of bone as a manufacturing material for assembled implants having multiple pieces, and taking on the challenges and disadvantages of bone such as those described in the Coates reference. "A prior art reference may be considered to teach away when 'a person of ordinary skill, upon reading the reference, would be discouraged from following the path set out in the reference, or would be led in a direction divergent from the path taken by the applicant."[147] Furthermore, "[a] prior art reference that 'teaches away' from the claimed invention is a significant factor to be considered in determining obviousness."[148] Thus, had the Examiner properly considered the Siebels reference as a whole, the Examiner would not made and maintained the obviousness rejection of claims 111-118 and 120-136.

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[144] Exhibit 15, at p. 4, Evidence Appendix.

[145] Exhibit 15, at p. 4, Evidence Appendix.

[146] See <u>In re Wesslau</u>, 147 USPQ 391, 393 (CCPA 1965); <u>Bausch & Lomb, Inc. v. Barnes-Hind Int'l, Inc.</u>, 230 USPQ 416, 420 (Fed. Cir. 1986); MPEP at § 2141.02.

[147] <u>Monarch Knitting v. Sulzer</u>, 139 F.3d 877, 885, 45 USPQ2d 1977, 1984 (Fed. Cir. 1998).

[148] MPEP §2145(X)(D)(1).

In light of the disclosures of the Siebels reference and the Coates reference when read in their entirety, there simply is no motivation or suggestion to combine the Siebels reference and the Coates reference to arrive at implants or portions of implants made from multiple pieces of cortical bone connected by cortical bone pins as disclosed and claimed in the present application. "A critical step in analyzing the patentability of claims pursuant to Section 103(a) is casting the mind back to the time of invention, to consider the thinking of one of ordinary skill in the art, guided only by the prior art references and the then-accepted wisdom in the field."[149] When this critical step is taken with respect to the Siebels reference and the Coates reference, it becomes apparent that given the "extremely difficult or impossible" setting of developing an implant from cortical bone as described in the Coates reference, it would not have been obvious to one of ordinary skill in the art to modify the single piece spacers of Coates in view of the multiple piece implants made from the braided or wound plastics of Siebels.

As evidenced by the foregoing discussion, the pending rejection under 35 U.S.C. §103(a) is improperly based on the picking and choosing of isolated elements from the prior art references. Additionally, the final Office action is improperly based on hindsight reconstruction of the cited references, using the present invention as a template. This hindsight application irreparably infects the final rejection in its entirety.

> To imbue one of ordinary skill in the art with knowledge of the invention in suit, when no prior art reference or references of record convey or suggest that knowledge, is to fall victim to the insidious effect of a hindsight syndrome wherein that which only the inventor taught is used against its teacher.[150]

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[149] In re Kotzab, 217 F.3d 1365, 1369, 55 USPQ2d 1313, 1316 (Fed. Cir. 2000); see also In re Dembiczak, 175 F.3d 994, 999, 50 USPQ2d 1614, 1617 (Fed. Cir. 1999).

[150] W.L. Gore & Associates, Inc. v. Garlock, Inc., 721 F.2d 1540, 1553, 220 USPQ 303, 313 (Fed. Cir. 1983); see Bausch and Lomb, Inc. v. Barnes-Hind, 796 F.2d 443, 448, 230 USPQ 416, 420 (Fed. Cir. 1986) (explaining that the district court "improperly viewed an isolated line" in a prior art reference in light of the teaching of the patent); In re Leonor, 395 F.2d 801, 804, 158 USPQ 20, 23 (C.C.P.A. 1968) ("[a]dmittedly, the Othmer affidavit and appellant's specification provide a ready guide for selecting and combining parts of the prior art processes. If, however, the prior art is considered *without* the Othmer affidavit and *without* appellant's teachings, no fact basis is established in the present record from which to support the legal conclusion [...of obviousness]").

The obviousness rejection over the Siebels reference in view of the Coates reference should therefore be withdrawn.

3. No Basis For A Reasonable Expectation Of Success Has Been Established With Respect to Combining the Siebels Reference and the Coates Reference To Arrive At The Subject Matter Of Claims 111-118 and 120-136

The MPEP states that "[r]easonable expectation of success is the standard with which obviousness is determined"[151] and requires that the reasonable expectation of success must be found in the prior art.[152] With respect to the present application, there has been no articulation of any basis for a reasonable expectation of success in the prior art related to using cortical bone to manufacture implants and portions of implants made from multiple pieces held in juxtaposition by cortical bone pins, as described and claimed by the Appellants. The failure to provide a reasonable expectation of success was legal error.

When addressing the issue of a reasonable expectation of success, the MPEP explains, "Obviousness does not require absolute predictability, however, at least some degree of predictability is required."[153] The MPEP further states, "Whether an art is predictable or whether the proposed modification or combination of the prior art has a reasonable expectation of success is determined at the time the invention was made."[154] When the cited prior art references are viewed in this context, it becomes apparent that they do not provide a reasonable expectation of success with respect to modifying the single piece cortical bone spacers disclosed in Coates in view of the multiple piece implants of Siebels. For example, given the difficulties with making bone grafts as described in the Coates reference, there would not have been a reasonable expectation of success that implants could be assembled from multiple pieces of cortical bone.

Further, both the Coates reference and the Siebels reference discuss the need for implant strength, but neither addresses whether multiple cortical bone pieces connected by retention pins

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[151] MPEP §2141.

[152] MPEP §2142.

[153] MPEP §2143.02.

[154] MPEP §2143.02.

would provide such strength. For example, the Coates reference expresses the concern that "[g]raft alone may not provide the stability required to withstand spinal loads," [155] and then states that "the spacers of this invention stimulate bone ingrowth like a bone graft and provide sufficient strength to support the vertebral column but avoid the disadvantages of both bone graft and metal implants...."[156] Similarly, the Siebels reference describes that the fiber reinforced plastic implants disclosed therein "are characterized in that they can be manufactured in an extraordinarily easy way, in which the fiber orientation equally imparts an optimal rigidity and strength to the implant." [157] Thus, while the Coates and Siebels references each describe that their own implants provide the necessary strength, neither one provides a basis from which it could be concluded that cortical bone pieces connected by cortical bone pins would successfully provide this property.

Because the combination of references in the pending obviousness rejection is not based upon any reasonable expectation of success found in the prior art, a prima facie case of obviousness has not been made and the rejection should be withdrawn.

4. The Combination of Coates and Siebels Does Not Teach All Of The Elements of Claims 114, 115, 127, 132 and 133

Claims 114 and 132 each recite retention pins "selected from the group consisting of cortical bone, a bioabsorbable synthetic polymer and titanium."[158] Claims 115, 127 and 133 each recite that the retention pin "is cortical bone."[159] The pending obviousness rejection of pending claims 114, 115, 127, 132 and 133 is improper because Coates and Siebels, either alone or in combination, do not teach retention pins having the elements recited in any of these claims.

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[155] Exhibit 18, at Col. 3, lns 18-19, Evidence Appendix.

[156] Exhibit 18, at Col. 5, lns 21-24, Evidence Appendix. (Emphasis added).

[157] Exhibit 19, English translation at p. 3, Evidence Appendix. (Emphasis added.)

[158] Claims 114 and 132, Claims Appendix.

[159] Claims 115, 127 and 133, Claims Appendix.

Under MPEP §2143.03, "To establish *prima facie* obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art."[160]

The Examiner has asserted that:

> Regarding at least claims 114-115, 123 and 127, lacking any criticality in the specification, the use of the claimed materials such as titanium in lieu of those taught by Seibels [sic] produce no advantage ad is considered an obvious matter of design choice. Additionally, Coates teaches the use of metal devices are foreign bodies which can never be fully incorporated in the fusion mass and produce stress shielding because the stiffness values do not match that of bone (column 2, lines 34 et seq.). Therefore, it would have been obvious to one having ordinary skill in the art to have constructed the pin out of cortical bone or cancellous bone which can be fully incorporated and does not produce stress shielding.[161]

These assertions and conclusions are not based upon proper consideration of the teachings of the cited references, and do not form a proper basis for the pending obviousness rejection.

As an initial matter, the only materials described in the Siebels reference from which the disks and/or anchoring pins described therein can be made are "fiber reinforced plastic"[162] and "carbon-fiber reinforced plastic."[163] For example, on page 6, the Siebels reference states that "the disks are made of a carbon-fiber reinforced plastic (CFP) whereby the anchoring means – according to the design of the implant – can consist of the same, or another material."[164] The Siebels reference, however, does not describe any other suitable materials from which the anchoring pins of Siebels can be made. Nor is there any discussion of the parameters or factors that should be considered when choosing the material from which to make the anchoring pins. There is thus no teaching within the Siebels reference to guide one of ordinary skill in the art in choosing any material for the anchoring pins other than carbon-fiber reinforced plastic.

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[160] MPEP §2143.03.

[161] Exhibit 15, at p. 8, Evidence Appendix.

[162] Exhibit 19, at p. 3, Evidence Appendix.

[163] Exhibit 19, at p. 6, Evidence Appendix.

[164] Exhibit 19, at pp. 3 and 6, Evidence Appendix.

Additionally, the teachings of the Coates reference, either alone or in combination with the teachings of Siebels, would not render retention pins of cortical bone, bioabsorbable synthetic polymers, or titanium obvious. As admitted by the Examiner, "Coates et al fails to teach said implant can comprise a first and second portion capable of being connected by a pin."[165] Instead, Coates teaches an implant made from a single piece of cortical bone.[166] The Coates reference thus does not provide any basis for utilizing retention pins, much less retention pins of cortical bone, a bioabsorbable synthetic polymer or titanium.

Furthermore, as discussed above, the Coates reference discusses many disadvantages associated with using both metals and bone as implant materials. As admitted by the Examiner, Coates lists disadvantages of metals as including that "metal devices are foreign bodies which can never be fully incorporated in the fusion mass and produce stress shielding because the stiffness values do not match that of bone."[167] The Coates reference also discusses many disadvantages with respect to the use of bone, including expressing concerns regarding the compressive strength and stability of bone implants, and states that developing a suitable implant "has been extremely difficult or impossible."[168] In view of these teachings, the Coates reference does not provide any basis for utilizing retention pins of cortical bone, a bioabsorbable synthetic polymer or titanium, such as those recited in pending claims 114, 115, 127, 132 and 133.

5. The Combination of Coates and Siebels Does Not Teach All Of The Elements of Claims 123, 124, and 128

Claim 123 recites that "one or more retention pins comprise a cancellous bone portion."[169] Claims 124 and 128 recite that the cancellous bone portion is treated with bone

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[165] Exhibit 15, at p. 7, Evidence Appendix.

[166] See, e.g., Exhibit 18, at Col. 11, lns 41-61, Evidence Appendix.

[167] Exhibit 15, at p. 8, Evidence Appendix.

[168] See, e.g., Exhibit 18, at Col. 2, ln 66 to Col. 3, ln 39, Evidence Appendix.

[169] Claim 123, Claims Appendix.

morphogenic protein (BMP).[170] The pending obviousness rejection of pending claims 114, 115, 127, 132 and 133 is improper because Coates and Siebels, either alone or in combination, do not teach retention pins having these elements.[171]

As discussed above, the Examiner has asserted that "it would have been obvious to one having ordinary skill in the art to have constructed the pin out of cortical bone or cancellous bone which can be fully incorporated and does not produce stress shielding."[172] With respect to treatment with bone morphogenic protein, the Examiner has asserted that "Coates et al teaches treating the spacer with BMP which would include the pins."[173] These assertions and conclusions are not based upon proper consideration of the teachings of the cited references, and do not form a proper basis for the pending obviousness rejection. For example, as discussed above, there is no basis within the Siebels reference to guide one of ordinary skill in the art in choosing any material for the anchoring pins other than carbon-fiber reinforced plastic. As additionally discussed above, the Coates reference does not provide any teachings with respect to retention pins, and teaches that the use of bone has disadvantages including issues with compressive strength and stability.

With respect to cancellous bone, in particular, the only discussion of cancellous bone in the cited references is in the Coates reference with respect to Cloward dowels. The Coates reference states that "the Cloward dowel is a circular graft made by drilling an allogenic or autogenic plug from the illium. Cloward dowels are bicortical, having porous cancellous bone between two cortical surfaces. Such dowels have relatively poor biomechanical properties, in particular a low compressive strength."[174] This discussion teaches away from implants having a cancellous bone portion, and so would not lead one of ordinary skill in the art to make an assembled bone implant utilizing a retention pin having a cancellous bone portion.

[170] Claims 124 and 128, Claims Appendix.

[171] MPEP §2143.03 ("To establish *prima facie* obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art").

[172] Exhibit 15, at p. 8, Evidence Appendix.

[173] Exhibit 15, at p. 8, Evidence Appendix.

[174] Exhibit 18, at Col. 3, lns 1-6, Evidence Appendix.

With respect to BMP, the Coates reference does describe "impregnating the graft with a solution including an osteogenic composition" such as BMP, which can be accomplished where the composition is "injected into the pores of the graft," "dripped onto the graft or the graft is soaked in a solution containing an effective amount of the composition to stimulate osteoinduction." [175] Contrary to the Examiner's assertions with respect to this teaching, however, the Coates reference does not provide a basis for treating a cancellous bone portion of a retention pin with BMP as recited in pending claims 124 and 128. As discussed above, the Coates reference does not teach implants having retention pins, so concluding that the Coates reference would lead one of ordinary skill in the art to utilize retention pins such as those recited in claims 124 and 128 is an improper oversimplification of Coates. Further, the teachings of Coates regarding BMP are related to impregnating the graft, and not to treating specific areas or portions of the graft such as a cancellous portion of a retention pin as recited in claims 124 and 128.

In view of the teachings of the Coates and Siebels references, it would not have been obvious to one of ordinary skill in the art to make assembled bone implants utilizing retention pins having a cancellous bone portion, as recited in claim pending 123, or such pins where the cancellous portion is treated with BMP, as recited in pending claims 124 and 128.

C. The Brantigan Reference In View of the Coates Reference Does Not Render the Claims 111-118 and 120-136 Obvious, and the Rejection Under 35 U.S.C. §103(a) Should Therefore Be Withdrawn

The Examiner erred in rejecting claims 111-118 and 120-136 under 35 U.S.C. §103(a) over U.S. Pat. No. 5,192,327 (hereinafter the "Brantigan" reference)[176] in view of the Coates reference where the cited references provides no basis to combine the reference teachings, nor a reasonable expectation of success with respect to making such a combination of the reference teachings, and where the cited references do not disclose each and every element of the rejected claims.

[175] Exhibit 18 at Col. 6, lns 25-26, lns 59-63, and Col. 8, lns 11-14.

[176] Exhibit 20, Evidence Appendix.

1. There is No Basis That Would Lead One of Ordinary Skill in the Art to Combine The Brantigan Reference and the Coates Reference, Nor is There Any Reasonable Expectation of Success

The March 15, 2006 Office Action admits that "Brantigan fails to teach the first and second portions are cortical bone."[177] The Office Action asserts, however, that "Brantigan teaches the device can be made of traditional orthopaedic implant materials"[178] and goes on to conclude that "[i]t would have been obvious to one having ordinary skill in the art to have utilized cortical bone which is a traditional orthopaedic implant material as taught by Coates for any of the elements of Brantigan."[179] The March 15, 2006 Office Action attempts to lend further support to the obviousness rejection by asserting that "Coates **specifically** states that the implant of Brantigan is flawed because the materials used (including metals) of Brantigan are too stiff which causes stress shielding, etc., as stated in the grounds of rejection. Coates in the very next paragraph teaches bone as an implant material 'avoid[s] the disadvantages of metal implants'; see column 2, lines 49 et seq."[180] The Appellants disagree with these characterizations of Coates and Brantigan. The conclusions reached in the March 15, 2006 Office Action are based upon improper generalizations that are not supported by the references when the references are properly considered in their entirety.

As pointed out in the March 15, 2006 Office Action, the abstract of Brantigan states that "The annular implants... are preferably made of a radiolucent material, preferably biocompatible carbon fiber reinforced polymers or are alternately made of traditional orthopaedic implant materials such as nickel, chromium, cobalt, stainless steel or titanium."[181] Notably, the

[177] Exhibit 15, at p. 9, Evidence Appendix. See also Exhibit 15, at p. 5, Evidence Appendix ("The Examiner notes that Brantigan does not teach cortical bone").

[178] Exhibit 15, at p. 9, Evidence Appendix.

[179] Exhibit 15, at p. 9, Evidence Appendix.

[180] Exhibit 15, at p. 5, Evidence Appendix. (Emphasis in original).

[181] Exhibit 20, at Abstract, Evidence Appendix.

Brantigan reference only lists metals in its exemplary listing of "traditional orthopaedic implant materials." Additionally, the Brantigan reference teaches that:

> The implants are preferably made of radiolucent material such as carbon fiber reinforced polymers known commercially as "Peek", (polyetherether ketone) or "Ultrapek" (polyether ketone, ether ketone, ketone). Alternately, polycarbonate, polyprophylene, polyethelyene and polysulfone type plastics material filled with glass or carbon fibers can be used. Such materials are supplied by ICI Industries of Wilmington, Del.; Fiber-Rite Corporation of Winona, Minn. or BASF Corporation.[182]

The Brantigan reference goes on to describe "a vertebrae prosthesis device of this invention composed of rigid biologically acceptable and inactive material, preferably a <u>radiolucent plastics material, inert metal and the like as described above</u>."[183] The Brantigan reference thus illustrates that metals were considered in the art to be traditional implant materials, and teaches a preference for radiolucent plastic materials in the implants disclosed by Brantigan. The Brantigan reference does not address the use of cortical bone. Nor does the Brantigan reference provide any suggestion that materials other than radiolucent plastics and inert metals could be utilized in the implants disclosed in Brantigan. The Brantigan reference thus does not provide any disclosure from which it would be obvious to one of ordinary skill in the art to make an assembled implant utilizing cortical bone, or from which one of ordinary skill in the art would have a reasonable expectation of success in making such an assembled implant.

The Coates reference also does not provide any basis from which it would be obvious to one of ordinary skill in the art to utilize cortical bone in an implant assembled from multiple pieces of cortical bone and held together by retention pins, as described and claimed in the instant application. The Examiner has asserted that Coates teaches bone as being a "traditional orthopaedic implant material,"[184] but the Coates reference does not use that terminology. Instead, this characterization of Coates is simply an attempt to improperly impose bone on the listing of implant materials provided in Brantigan. When the actual teachings of Coates are

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[182] Exhibit 20, at Col. 3, lns 9-18, Evidence Appendix.

[183] Exhibit 20, at Col. 4, lns 2-5, Evidence Appendix. (Emphasis added).

[184] Exhibit 15, at p. 9, Evidence Appendix.

considered, it becomes clear that the Coates reference does not teach bone as a general substitute for metals, and also that the Coates reference would not lead one of ordinary skill to utilize cortical bone in the implants of Brantigan.

Contrary to the assertions of the Examiner, the Coates reference does not provide a general statement that bone can be used in any type of implant instead of metal. The Coates reference does specifically addresses the Brantigan reference with respect to its teachings of metal implants, and further discusses several disadvantages encountered with such metal implants.[185] The Coates reference then states, "Various bone grafts and bone graft substitutes have also been used to promote osteogenesis and to avoid the disadvantages of metal implants,"[186] and describes some advantages of bone such as replacement over time, avoiding stress shielding and lack of scattering during postoperative imaging.[187] The Coates reference, however, also describes disadvantages and drawbacks associated with bone implants. The Coates reference states, "Unfortunately, the use of bone grafts presents several disadvantages" including that "[g]raft alone may not provide the stability required to withstand spinal loads."[188] For example, Coates describes that Cloward dowels have "relatively poor biomechanical properties, in particular low compressive strength."[189] The Coates reference goes on to state:

> Several attempts have been made to develop a bone graft substitute which avoids the disadvantages of metal implants and bone grafts while capturing advantages of both. In each case, developing an implant having the biomechanical properties of metal and the biological properties of bone without the disadvantages of either has been extremely difficult or impossible.[190]

It is with this background, that the Coates reference then discloses its implants made from a single piece of cortical bone and states that one "benefit of this invention is that it allows the

[185] Exhibit 18, at Col. 2, lns 40-48, Evidence Appendix.

[186] Exhibit 18, at Col. 2, lns 49-65, Evidence Appendix.

[187] Exhibit 18, at Col. 2, lns 49-65, Evidence Appendix.

[188] Exhibit 18, at Col. 3, lns 32, Evidence Appendix.

[189] Exhibit 18, at Col. 2, ln 66 to Col. 3, ln 9, Evidence Appendix

[190] Exhibit 18, at Col. 3, lns 33-39, Evidence Appendix.

use of bone grafts without the need for metal cages or internal fixation, <u>due to the compressive strength of the spacer</u> and the means for resisting migration."[191] Significantly, even though the Coates reference specifically discusses the Brantigan reference, the Coates reference does not provide any discussion suggesting that the bone implants disclosed therein could be made from connecting multiple pieces of cortical bone in a manner similar to the metal or plastic implants of Brantigan. Instead, the Coates reference stresses the need for implant strength and presents its single piece implants as a solution to the difficulties experienced in the art in developing a bone implant having the requisite strength. One of ordinary skill would thus not have any reasonable expectation that a combination of Brantigan and Coates would be successful. Furthermore, the Coates reference teaches away from a combination of Coates and Brantigan because, in light of the teachings of Coates, one of ordinary skill would have been discouraged from making an assembled implant comprising a first and second cortical bone portion connected by one or more retention pins.[192]

"A critical step in analyzing the patentability of claims pursuant to Section 103(a) is casting the mind back to the time of invention, to consider the thinking of one of ordinary skill in the art, guided only by the prior art references and the then-accepted wisdom in the field." <u>In re Kotzab</u>, 217 F.3d 1365, 1369, 55 USPQ2d 1313, 1316 (Fed. Cir. 2000); <u>see also</u> <u>In re Dembiczak</u>, 175 F.3d 994, 999, 50 USPQ2d 1614, 1617 (Fed. Cir. 1999). Furthermore, the cited prior art as a whole must be considered, taking into account the negative teachings that would lead a person of ordinary skill away from the patented invention, as well as the teachings unfavorable to patentability. The Federal Circuit held in the *Dow* case:

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[191] Exhibit 18, at Col. 4, lns 13-16, Evidence Appendix. (Emphasis added).

[192] <u>See</u> <u>Monarch Knitting v. Sulzer</u>, 139 F.3d 877, 885, 45 USPQ2d 1977, 1984 (Fed. Cir. 1998)("A prior art reference may be considered to teach away when 'a person of ordinary skill, upon reading the reference, would be discouraged from following the path set out in the reference, or would be led in a direction divergent from the path taken by the applicant"). See also MPEP §2145(X)(D)(1).("A prior art reference that 'teaches away' from the claimed invention is a significant factor to be considered in determining obviousness").

> <u>In determining whether such a suggestion can fairly be gleaned from the prior art, the full field of the invention must be considered</u>; for the person of ordinary skill is charged with knowledge of the entire body of technological literature, including that which might lead away from the claimed invention. The Commissioner argues that since the PTO is no longer relying on Farmer or the Bacon and Farmer article, the applicant is creating a "straw man". It is indeed pertinent that these references teach against the present invention. Evidence that supports, rather than negates, patentability must be fairly considered. [193]

When these considerations are taken into account with respect to the Brantigan reference and the Coates reference, it becomes apparent that it would not have been obvious to one of ordinary skill in the art to combine the Brantigan reference and the Coates reference in the manner suggested by the Examiner to arrive at assembled implants made from multiple pieces of cortical bone connected by cortical bone pins as disclosed and claimed in the present application. The Appellants therefore request that the pending obviousness rejection over Brantigan in view of Coates be withdrawn.

2. A Combination of Brantigan and Coates Does Not Teach Each and Every Element of Pending Independent Claim 111

Pending independent claim 111 recites an assembled bone implant suitable for implantation into a patient comprising a first cortical bone portion and a second cortical bone portion, "said first cortical bone portion and said second cortical bone portion having one or more <u>circular through holes</u> sized and positioned for receiving one or more retention pins for connecting said first cortical bone portion to said second cortical bone portion; <u>and one or more retention pins of appropriate diameter for fitting said through holes</u> and connecting said first cortical bone portion to said second cortical bone portion and forming said assembled bone implant as a unitary body outside of said patient, said assembled bone implant being suitable for implantation into said patient."[194] Even if the Brantigan and Coates references are combined, the

[193] *In re Dow Chemical Co.*, 837 F.2d 469, 473, 5 U.S.P.Q.2d (BNA) 1529, 1532 (Fed. Cir. 1988)(emphasis added).

[194] Claim 111, Claims Appendix. (Emphasis added).

combination does not teach the elements of cortical bone portions having "circular through holes" and "one or more retention pins of appropriate diameter for fitting said through holes" as recited in claim 111. The pending obviousness rejection of independent claim 111, as well as claims 112-125 that depend therefrom, is therefore improper under MPEP §2143.03 because "[t]o establish *prima facie* obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art."[195]

As an initial matter, The Examiner has acknowledged that the Coates reference "fails to teach said implant can comprise a first and second portion capable of being connected by a pin."[196] Accordingly, the elements of a first cortical bone portion and a second cortical bone portion "having one or more circular through holes" and "one or more retention pins of appropriate diameter for fitting said through holes and connecting said first cortical bone portion to said second cortical bone portion" are thus not disclosed by the Coates reference.

With respect to claim 111, the Examiner has taken the position that elements 14 and 24 of Brantigan are "circular" when circular is defined as "of or relating to a circle."[197] Additionally, the March 15, 2006 Office Action states that, with respect to Brantigan, "the entire opening can be interpreted as the through hole."[198] While the Patent Office is required to give patent claims their broadest <u>reasonable</u> construction during prosecution,[199] the pending rejection is based upon constructions that are unreasonably broad, and should therefore be withdrawn.

A construction of the term "circular" as encompassing things other than actual circles, such as semi-circles, is inconsistent with the specification of the instant application. For example, when claim 111 was amended to recite "one or more circular through holes sized and positioned for receiving one or more retention pins" and "one or more retention pins of appropriate diameter for fitting said through holes and connecting said first cortical bone portion

[195] MPEP §2143.03.

[196] Exhibit 15, at p. 7, Evidence Appendix.

[197] Exhibit 15, at p. 5, Evidence Appendix.

[198] Exhibit 15, at p. 5, Evidence Appendix.

[199] MPEP §904.01 ("During patent examination, the claims are given the broadest reasonable interpretation consistent with the specification").

to said second cortical bone," specific reference was made to circular through holes 701-704 of FIG. 7A of the instant application. Through holes 701-704 of Fig. 7A are complete circles through the illustrated implant, and are notably distinct from the central opening illustrated in the implant of Fig. 7A. As disclosed in the instant application, therefore, a circular through hole has a cross section that is a circle. Furthermore, a retention pin having of appropriate diameter for fitting said through hole would correspondingly be a circular retention pin that fits the circular through hole.

In contrast, the Brantigan reference does not illustrate circular through holes or retention pins that are of appropriate diameter for fitting said through holes. Figures 1-5 of the Brantigan reference illustrate the embodiments referenced by the Examiner with respect to elements 14 and 24, as well as "the entire opening" which corresponds to central apertures 11d and 21d.

Elements 14 and 24 are grooves in the side walls of the interior faces of the Brantigan implants, and are not circular though holes as recited in pending claim 111. The grooves of Brantigan are illustrated as being semi-circular in cross section.[200] Additionally, the Brantigan reference describes "upstanding open ended vertical <u>grooves</u> 14 preferably of <u>fragmental cylindrical configuration</u>."[201]

The Examiner has apparently recognized that the grooves of Brantigan are not circular through holes, and has therefore asserted that "the entire opening can be interpreted as the through hole."[202] Central apertures 11d and 21d of Brantigan are neither through holes nor circular. As noted above, Figure 7A of the instant application illustrates that the through holes are distinct from the central opening of the implant. Furthermore, central aperture 11d of Brantigan is an oval and central opening 21d is a hemi-oval.[203]

As a final matter, the connecting bars of Brantigan are not retention pins of appropriate diameter for fitting said through holes as recited in claim 111. Brantigan discloses that the

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[200] <u>See</u> Exhibit 20, at Figs. 1-5, Evidence Appendix.

[201] Exhibit 20, at Col. 4, lns 23-25, Evidence Appendix. (Emphasis added).

[202] Exhibit 15, at p. 5, Evidence Appendix.

[203] Exhibit 20, at Figures 1-5, Evidence Appendix. <u>See</u> <u>also</u> Exhibit 20, at Col. 4, lns 5-14 and 57-64.

"grooves are provided for mounting a rectangular connecting bar 15 shown in FIG. 3. This bar 15 has flat side faces 15a, rounded side edges 15b to snugly fit the grooves 14 and top and bottom end edges 15c."[204] Figures 4 and 5 of Brantigan illustrate that the ends of rectangular connecting bar 15 fit into semi-circular grooves 14 or 24, but that the main body of the rectangular connecting bar traverses the width of the central aperture 11d or 21d between the grooves 14 or 24 on either side of the central aperture. The rectangular connecting bar thus extends beyond the grooves 14 or 24, and thus is not "of appropriate diameter for fitting said through holes" if the grooves are interpreted as being through holes. Furthermore, the rectangular connecting bar traverses a portion of the central aperture 11d or 21d, but does not fill the space defined by the central aperture, and is thus not "of appropriate diameter for fitting said through holes" if the central aperture is interpreted as being a through hole.

The assertion that pending independent claim 111 encompasses the semi-circular grooves and oblong retention bars, or the central apertures, of Brantigan is thus not sound. If pending independent claim 111 is properly construed, it is distinguished over Brantigan, which does not show "circular through holes," or "one or more retention pins of appropriate diameter for fitting said through holes" as recited in claim 111. Because all of the elements of claim 111 are not found in the cited references, a prima facie case of obviousness has not been made with respect to pending independent claim 111 and the claims that depend therefrom. The pending obviousness rejection over Brantigan in view of Coates should therefore be withdrawn with respect to claims 111-125.

3. The Combination of Coates and Brantigan Does Not Teach All Of The Elements of Claims 123, 124, and 128

Claim 123 recites that "one or more retention pins comprise a cancellous bone portion."[205] Claims 124 and 128 recite that the cancellous bone portion is treated with bone

[204] Exhibit 20, at Col. 4, lns 25-29, Evidence Appendix. (Emphasis added).

[205] Claim 123, Claims Appendix.

morphogenic protein (BMP).[206] The pending obviousness rejection of pending claims 114, 115, 127, 132 and 133 is improper because Coates and Brantigan, either alone or in combination, do not teach retention pins having these elements.[207]

The Examiner has asserted that:

> Regarding at least claims 114-115, 123 and 127, the combination at least teaches titanium or cortical bone, lacking any criticality in the specification, the use of the claimed materials such as titanium in lieu of those taught by [sic] references produce no advantage ad is considered an obvious matter of design choice. Additionally, Coates teaches the use of metal devices are foreign bodies which can never be fully incorporated in the fusion mass and produce stress shielding because the stiffness values do not match that of bone (column 2, lines 34 et seq.). Therefore, it would have been obvious to one having ordinary skill in the art to have constructed the pin out of cortical bone or cancellous bone which can be fully incorporated and does not produce stress shielding.[208]

With respect to treatment with bone morphogenic protein, the Examiner has asserted that "Coates et al teaches treating the spacer with BMP which would include the pins."[209] These assertions and conclusions are not based upon proper consideration of the teachings of the cited references, and do not form a proper basis for the pending obviousness rejection.

For example, as discussed above, the Brantigan reference discloses implants made from carbon fiber reinforced polymers or various metals."[210] The Brantigan reference does not disclose the use of cancellous bone as materials for any component of the implants disclosed therein. Additionally, with respect to claims 123 and 124 in particular, the Brantigan reference does not teach retention pins in accordance with the limitations of independent claim 111, from which claims 123 and 124 ultimately depend.

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[206] Claims 124 and 128, Claims Appendix.

[207] MPEP §2143.03 ("To establish *prima facie* obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art").

[208] Exhibit 15, at p. 10, Evidence Appendix.

[209] Exhibit 15, at p. 8, Evidence Appendix.

[210] Exhibit 20, at Abstract, Evidence Appendix.

Furthermore, as discussed above, the Coates reference does not provide any teachings with respect to retention pins, and teaches that the use of bone has disadvantages including issues with compressive strength and stability. With respect to cancellous bone, in particular, the only discussion of cancellous bone in the cited references is in the Coates reference with respect to Cloward dowels. The Coates reference states that "the Cloward dowel is a circular graft made by drilling an allogenic or autogenic plug from the illium. Cloward dowels are bicortical, having porous cancellous bone between two cortical surfaces. Such dowels have relatively poor biomechanical properties, in particular a low compressive strength."[211] This discussion teaches away from implants having a cancellous bone portion, and so would not lead one of ordinary skill in the art to make an assembled bone implant utilizing a retention pin having a cancellous bone portion.

With respect to BMP, the Coates reference does describe "impregnating the graft with a solution including an osteogenic composition" such as BMP, which can be accomplished where the composition is "injected into the pores of the graft," "dripped onto the graft or the graft is soaked in a solution containing an effective amount of the composition to stimulate osteoinduction." [212] Contrary to the Examiner's assertions with respect to this teaching, however, the Coates reference does not provide a basis for treating a cancellous bone portion of a retention pin with BMP as recited in pending claims 124 and 128. As discussed above, the Coates reference does not teach implants having retention pins, so concluding that the Coates reference would lead one of ordinary skill in the art to utilize retention pins such as those recited in claims 124 and 128 is an improper oversimplification of Coates. Further, the teachings of Coates regarding BMP are related to impregnating the graft, and not to treating specific areas or portions of the graft such as a cancellous portion of a retention pin as recited in claims 124 and 128.

In view of the teachings of the Coates and Brantigan references, it would not have been obvious to one of ordinary skill in the art to make assembled bone implants utilizing retention

[211] Exhibit 18, at Col. 3, lns 1-6, Evidence Appendix.

[212] Exhibit 18 at Col. 6, lns 25-26, lns 59-63, and Col. 8, lns 11-14.

pins having a cancellous bone portion, as recited in claim pending 123, or such pins where the cancellous portion is treated with BMP, as recited in pending claims 124 and 128.

CONCLUSION

In view of the arguments and evidence provided herein by the Appellants, all bases for the rejection of claims 111-118, 120-123 and 129-136 under 35 U.S.C. § 102(b) in view of Albee, the rejection of claims 111-118 and 120-136 under 35 U.S.C. § 103(a) with respect to Coates in view of Siebels, and the rejection of claims 111-118 and 120-136 under 35 U.S.C. § 103(a) with respect to Brantigan in view of Coates have been rebutted. For these reasons, the Appellants respectfully request the withdrawal of all bases for rejection and the allowance of pending claims 111-118, and 120-136.

Appellants believe that a fee of $500.00 is currently due under 37 C.F.R. §41.20(b)(2) in conjunction with the filing of this brief, and that a fee if $1590.00 is currently due in conjunction with the four month Petition for Extension of time submitted herewith under 37 C.F.R. §1.17(a)(4). The total fees thus believed to be due at this time is $2090.00. The Commissioner is authorized to charge the amount of $2090.00, and any additional fees that may be due, or to credit any overpayment, to account number 13-0017, in the name of McAndrews, Held & Malloy, Ltd.

Dated: March 12, 2007

Respectfully submitted,

McANDREWS, HELD & MALLOY, LTD.

By: ______________________

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Evidence Appendix:
Statement Regarding Evidence Entered

The Evidence Appendix contains Exhibits 1-20, each of which is part of the prosecution history in this matter and has been entered into the record. The Exhibits are individually listed below, along with a notation regarding the date that each Exhibit was made of record. The dates listed as the Record Date below include the mailing date for Office Actions, the filing date for Responses, and the date on which references were first relied upon in forming a rejection.

Exhibit ID	Exhibit Content	Record Date
Exhibit 1	Application as Filed	July 13, 2001
Exhibit 2	Notice to File Missing Parts of Nonprovisional Application	December 10, 2001
Exhibit 3	Repose to Notice to File Missing Parts of Application and Petition to Make Application Under 37 CFR §1.47(a)	March 11, 2002
Exhibit 4	37 CFR 1.607(a)(4) Amendment (Preliminary Amendment)	January 30, 2002 (date received by OIPE)
Exhibit 5	Office Action (Election/Restriction)	August 6, 2003
Exhibit 6	Preliminary Amendment and Response to Restriction Under 35 U.S.C. §121	September 11, 2003
Exhibit 7	Office Action (Notice of Non-Complaint Response)	October 8, 2003
Exhibit 8	Second Preliminary Amendment and Response to A Notice of Non-Compliant Response	February 16, 2004
Exhibit 9	Office Action	March 16, 2004
Exhibit 10	Amendment and Response under 37 C.F.R. § 1.111 (With Attachments A-E)	September 16, 2004

Exhibit ID	Exhibit Content	Record Date
Exhibit 11	Office Action (With European Patent Application No. 0517030 and Translation Attached)	December 15, 2004
Exhibit 12	Amendment and Response under 37 C.F.R. § 1.111 (With Attachments A-B)	April 13, 2005
Exhibit 13	Office Action	June 17, 2005
Exhibit 14	Request for Continued Examination Under 37 C.F.R. § 1.114 (With Attachments A-B)	December 19, 2005
Exhibit 15	Office Action	March 15, 2006
Exhibit 16	Notice of Appeal under 37 C.F.R. § 1.191	September 11, 2006
Exhibit 17	Fred H. Albee, "Bone Surgery With Machine Tools," Scientific American, Vol. 154, No. 4, pp. 178-181 (1936)	December 15, 2004
Exhibit 18	U.S. Pat. No. 5,989,289	March 16, 2004
Exhibit 19	European Patent Application No. 0517030 (with Translation attached)	March 16, 2004
Exhibit 20	U.S. Pat. No. 5,192,327	December 15, 2004

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PTO/SB/05 (03-01)
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UTILITY PATENT APPLICATION TRANSMITTAL

(Only for new nonprovisional applications under 37 CFR 1.53(b))

Attorney Docket No.	TB-104IACA
First Inventor	Grooms *et al.*
Title	Cortical Bone Cervical Smith-Robinson Fusion Implant
Express Mail Label No.	ET112635750US

APPLICATION ELEMENTS

See MPEP chapter 600 concerning utility patent application contents.

ADDRESS TO: Assistant Commissioner for Patents
Box Patent Application
Washington, DC 20231

1. [X] Fee Transmittal Form (e.g., PTO/SB/17) *(Submit an original and a duplicate for fee processing)*
2. [ ] Applicant claims small entity status. See 37 CFR 1.27.
3. [X] Specification [*Total Pages* 37] *(preferred arrangement set forth below)*
   - Descriptive title of the invention
   - Cross Reference to Related Applications
   - Statement Regarding Fed sponsored R & D
   - Reference to sequence listing, a table, or a computer program listing appendix
   - Background of the Invention
   - Brief Summary of the Invention
   - Brief Description of the Drawings *(if filed)*
   - Detailed Description
   - Claim(s)
   - Abstract of the Disclosure
4. [X] Drawing(s) *(35 U.S.C. 113)* [*Total Sheets* 22]
5. Oath or Declaration [*Total Sheets* 2]
   a. [ ] Newly executed (original or copy)
   b. [ ] Copy from a prior application (37 CFR 1.63 (d)) *(for continuation/divisional with Box 18 completed)*
      i. [ ] DELETION OF INVENTOR(S) Signed statement attached deleting inventor(s) named in the prior application, see 37 CFR 1.63(d)(2) and 1.33(b).
6. [ ] Application Data Sheet. See 37 CFR 1.76
7. [ ] CD-ROM or CD-R in duplicate, large table or Computer Program (Appendix)
8. Nucleotide and/or Amino Acid Sequence Submission *(if applicable, all necessary)*
   a. [ ] Computer Readable Form (CRF)
   b. Specification Sequence Listing on:
      i. [ ] CD-ROM or CD-R (2 copies); or
      ii. [ ] paper
   c. [ ] Statements verifying identity of above copies

ACCOMPANYING APPLICATION PARTS

9. [ ] Assignment Papers (cover sheet & document(s))
10. [ ] 37 CFR 3.73(b) Statement *(when there is an assignee)* [X] Power of Attorney
11. [ ] English Translation Document *(if applicable)*
12. [ ] Information Disclosure Statement (IDS)/PTO-1449 [ ] Copies of IDS Citations
13. [ ] Preliminary Amendment
14. [X] Return Receipt Postcard (MPEP 503) *(Should be specifically itemized)*
15. [ ] Certified Copy of Priority Document(s) *(if foreign priority is claimed)*
16. [ ] Nonpublication Request under 35 U.S.C. 122 (b)(2)(B)(i). Applicant must attach form PTO/SB/35 or its equivalent.
17. [X] Other: Copy of Petition for a Four-month Extension of Time for parent Application No. 09/701,933

18 If a CONTINUING APPLICATION, *check appropriate box, and supply the requisite information below and in a preliminary amendment, or in an Application Data Sheet under 37 CFR 1.76:*

[X] Continuation [ ] Divisional [ ] Continuation-in-part (CIP) of prior application No.: 09/701,933

Prior application information: *Examiner* Unknown *Group Art Unit:* 5611

For CONTINUATION or DIVISIONAL APPS only: The entire disclosure of the prior application, from which an oath or declaration is supplied under Box 5b, is considered a part of the disclosure of the accompanying continuation or divisional application and is hereby incorporated by reference. The incorporation can only be relied upon when a portion has been inadvertently omitted from the submitted application parts.

19. CORRESPONDENCE ADDRESS

[ ] *Customer Number or Bar Code Label* *(Insert Customer No. or Attach bar code label here)* *or* [ ] *Correspondence address below*

Name	Timothy H. Van Dyke		
Address	Bencen & Van Dyke, P.A., 1630 Hillcrest Street, Orlando, FL 32803 USA		
Telephone	407-228-0328	*Fax*	407-228-0329

I hereby certify that this correspondence is being deposited with the United States Postal Service "Express Mail Post Office to Addressee" service with sufficient postage under 37 CFR 1.10 on the date indicated below and is addressed to: Assistant Commissioner for Patents, Box Patent Application, Washington, D.C. 20231.

By [signature] *Express Mail No:* ET112635750US *Date* 7-13-2001

Name (Print/type)	Timothy H. Van Dyke	*Registration No. (Attorney/Agent)*	43218
Signature	[signature]	*Date*	7-13-2001

PTO/SB/17 (11-00)
Approved for use through 10/31/2002. OMB 0651-0032
U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

FEE TRANSMITTAL for FY 2001

Patent fees are subject to annual revision.

TOTAL AMOUNT OF PAYMENT	($) 2,114.00

Complete if Known	
Application Number	Unknown
Filing Date	7/13/2001
First Named Inventor	Grooms *et al.*
Examiner Name	Unknown
Group Art Unit	Unknown
Attorney Docket No.	TB-104IACA

METHOD OF PAYMENT

1. ☐ The Commissioner is hereby authorized to charge indicated fees and credit any overpayments to:

Deposit Account Number: ____

Deposit Account Name: ____

☐ Charge Any Additional Fee Required Under 37 CFR 1.16 and 1.17

☐ Applicant claims small entity status. See 37 CFR 1.27

2. ☐ Payment Enclosed:
☐ Check ☐ Credit Card ☐ Money Order ☐ Other

FEE CALCULATION

1. BASIC FILING FEE

Large Entity Fee Code	Large Entity Fee ($)	Small Entity Fee Code	Small Entity Fee ($)	Fee Description	Fee Paid
101	710	201	355	Utility filing fee	710.00
106	320	206	160	Design filing fee	
107	490	207	245	Plant filing fee	
108	710	208	355	Reissue filing fee	
114	150	214	75	Provisional filing fee	

SUBTOTAL (1) ($) 710.00

2. EXTRA CLAIM FEES

			Extra Claims		Fee from Below		Fee Paid
Total Claims	58	-20** =	38	x	18.00	=	684.00
Independent Claims	12	- 3** =	9	x	80.00	=	720.00
Multiple Dependent						=	

Large Entity Fee Code	Large Entity Fee ($)	Small Entity Fee Code	Small Entity Fee ($)	Fee Description
103	18	203	9	Claims in excess of 20
102	80	202	40	Independent claims in excess of 3
104	270	204	135	Multiple dependent claim, if not paid
109	80	209	40	**Reissue independent claims over original patent
110	18	210	9	**Reissue claims in excess of 20 and over original patent

SUBTOTAL (2) ($)1,404.00

** or number previously paid, if greater; For Reissues, see above

FEE CALCULATION (continued)

3. ADDITIONAL FEES

Large Entity Fee Code	Large Entity Fee ($)	Small Entity Fee Code	Small Entity Fee ($)	Fee Description	Fee Paid
105	130	205	65	Surcharge – late filing fee or oath	
127	50	227	25	Surcharge – late provisional filing fee or cover sheet	
139	130	139	130	Non-English specification	
147	2,520	147	2,520	For filing a request for *ex parte* reexamination	
112	920*	112	920*	Requesting publication of SIR prior to Examiner action	
113	1,840*	113	1,840*	Requesting publication of SIR after Examiner action	
115	110	215	55	Extension for reply within first month	
116	390	216	195	Extension for reply within second month	
117	890	217	445	Extension for reply within third month	
118	1,390	218	695	Extension for reply within fourth month	
128	1,890	228	945	Extension for reply within fifth month	
119	310	219	155	Notice of Appeal	
120	310	220	155	Filing a brief in support of an appeal	
121	270	221	135	Request for oral hearing	
138	1,510	138	1,510	Petition to institute a public use proceeding	
140	110	240	55	Petition to revive – unavoidable	
141	1,240	241	620	Petition to revive – unintentional	
142	1,240	242	620	Utility issue fee (or reissue)	
143	440	243	220	Design issue fee	
144	600	244	300	Plant issue fee	
122	130	122	130	Petitions to the Commissioner	
123	50	123	50	Processing fee under 37 CFR 1.17(q)	
126	180	126	180	Submission of Information Disclosure Stmt	
581	40	581	40	Recording each patent assignment per property (times number of properties)	
146	710	246	355	Filing a submission after final rejection (37 CFR § 1.129(a))	
149	710	249	355	For each additional invention to be examined (37 CFR § 1.129(b))	
179	710	279	355	Request for Continued Examination (RCE)	
169	900	169	900	Request for expedited examination of a design application	

Other fee (specify) ____

*Reduced by Basic Filing Fee Paid

SUBTOTAL (3) ($)0.00

SUBMITTED BY				Complete *(if applicable)*	
Name (Print/Type)	Timothy H. Van Dyke	*Registration No. (Attorney/Agent)*	43218	*Telephone*	407-228-0328
Signature	*[signature]*			*Date*	7-13-2001

WARNING: Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038.

DECLARATION AND POWER OF ATTORNEY FOR PATENT APPLICATION	ATTORNEY DOCKET NO. TB-104IACA

As a below named inventor, I hereby declare that:
My residence/post office address and citizenship are as stated below next to my name;
I believe I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter which is claimed and for which a patent is sought on the invention entitled:
Cortical Bone Cervical Smith-Robinson Fusion Implant
the specification of which is attached hereto unless the following box is checked:

( ) was filed on _______________ as US Application Serial No. or PCT International Application Number _______________ and was amended on _______________ (if applicable).

I hereby state that I have reviewed and understood the contents of the above-identified specification, including the claims, as amended by any amendment(s) referred to above. I acknowledge the duty to disclose all information which is material to patentability as defined in 37 CFR 1.56.

Foreign Application(s) and/or Claim of Foreign Priority

I hereby claim foreign priority benefits under Title 35, United States Code Section 119 of any foreign application(s) for patent or inventor(s) certificate listed below and have also identified below any foreign application for patent or inventor(s) certificate having a filing date before that of the application on which priority is claimed:

COUNTRY	APPLICATION NUMBER	DATE FILED	PRIORITY CLAIMED UNDER 35 U.S.C. 119
			YES:____ NO:____
			YES:____ NO:____

Provisional Application

I hereby claim the benefit under Title 35, United States Code Section 119(e) of any United States provisional application(s) listed below:

APPLICATION SERIAL NUMBER	FILING DATE

U.S. Priority Claim

I hereby claim the benefit under Title 35, United States Code, Section 120 of any United States application(s) listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States application in the manner provided by the first paragraph of Title 35, United States Code Section 112, I acknowledge the duty to disclose material information as defined in Title 37, Code of Federal Regulations, Section 1.56(a) which occurred between the filing date of the prior application and the national or PCT international filing date of this application:

APPLICATION SERIAL NUMBER	FILING DATE	STATUS(patented/pending/abandoned)
09/701,933	8/25/1998	Pending
08/920,630	8/27/1997	Pending

POWER OF ATTORNEY:

As a named inventor, I hereby appoint the following attorney(s) and/or agent(s) listed below to prosecute this application and transact all business in the Patent and Trademark Office connected therewith.

Timothy H. Van Dyke, Reg. No. 43218

Send Correspondence to:	Direct Telephone Calls To:
Timothy H. Van Dyke Bencen & Van Dyke, P.A. 1630 Hillcrest Street Orlando, Florida 32803	Timothy H. Van Dyke 407-228-0328

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Full Name of Inventor: Jamie M. Grooms **Citizenship:** USA

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_______________________________ _______________________________

Inventor's Signature **Date**

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Inventor's Signature Date

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Inventor's Signature Date

Full Name of Inventor: Citizenship:

Residence:

Post Office Address:

Inventor's Signature Date

Full Name of Inventor: Citizenship:

Residence:

Post Office Address:

Inventor's Signature Date

Full Name of Inventor: Citizenship:

Residence:

Post Office Address:

Inventor's Signature Date

PETITION FOR EXTENSION OF TIME UNDER 37 CFR 1.136(a)

Docket Number (Optional)
TB-104IA US

In re Application of: Sander *et al.*

Application Number: 09/701,933 | Filed: 8/25/1998

For Cortical Bone Cervical Smith-Robinson Fusion Implant

Group Art Unit: 5611 | Examiner: Unknown

This is a request under the provisions of 37 CFR 1.136(a) to extend the period for filing a reply in the above identified application.

The requested extension and appropriate non-small-entity fee are as follows (check time period desired):

	One month (37 CFR 1.17(a)(1))	$ 110.00
	Two months (37 CFR 1.17(a)(2))	$ 390.00
	Three months (37 CFR 1.17(a)(3))	$ 890.00
☒	Four months (37 CFR 1.17(a)(4))	$ 1,390.00
	Five months (37 CFR 1.17(a)(5))	$ 1,890.00

Applicant claims small entity status. See 37 CFR 1.27. Therefore the fee amount shown above is reduced by one-half, and the resulting fee is: $_____.

☒ A check in the amount of the fee is enclosed.

Payment by credit card. Form PTO-2038 is attached.

The Commissioner has already been authorized to charge fees in this application to a Deposit Account.

The Commissioner is hereby authorized to charge any fees which may be required, or credit any overpayment, to Deposit Account Number __________________.
I have enclosed a duplicate copy of this sheet.

I am the

applicant/inventor

assignee of record of the entire interest. See 37 CFR 3.71.
Statement under 37 CFR 3.73(b) is enclosed. (Form PTO/SB/96).

☒ attorney or agent of record.

attorney or agent under 37 CFR 1.34(a).
Registration number if acting under 37 CFR 1.34(a) __________________.

WARNING: Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038.

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope with sufficient postage addressed to: Assistant Commissioner for Patents, Washington, D.C. 20231.

Date of Deposit: 7/13/2001 Typed Name: Timothy H. Van Dyke

Signature:

Signature 7-13-2001
Date

Timothy H. Van Dyke
Typed or printed name

NOTE: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required. Submit multiple forms if more than one signature is required, see below.

☒ Total of 1 forms are submitted.

DESCRIPTION

CORTICAL BONE CERVICAL SMITH-ROBINSON FUSION IMPLANT

Crossreference to Related Applications

This application is a continuation of currently pending Application No. 09/701,933, filed August 25, 1998, which is a continuation-in-part of currently pending Application No. 08/920,630 filed August 30, 1997, to which Applicants claim the benefit of priority under 35 USC §120.

1.0 Background of the Invention

1.1 Field of the Invention:

This invention relates to a cortical bone implant for use in cervical Smith-Robinson vertebral fusion procedures, as well as methods for the manufacture and use thereof. Furthermore, this application relates to an assembled implant comprised of two or more individual segments fastened together.

1.2 Background Art:

Since at least the mid to late 1950's anterior cervical spinal fusions have been performed in order to alleviate chronic neck, arm and shoulder pain caused by trauma, disc herniation, or spondylosis (Robinson and Smith, 1955; Smith and Robinson, 1958). The classic procedure referred to as the Smith-Robinson cervical fusion employs a horseshoe-shaped graft to promote vertebral fusion (Robinson *et al.*, 1962). The Cloward technique employs a cancellous bone dowel (Cloward, 1958), and the Bailey-Badgley procedure uses a strut (Bailey and Badgley, 1960). In a study comparing the compressive load capacity of the various implants used according to these procedures, it was found that the Smith-Robinson graft could sustain loads up to 344 N, the Cloward dowel could sustain

loads of up to 188 N, and the Bailey-Badgley type could sustain loads up to 195 N, (White and Hirsch, 1972). In a modified Smith-Robinson procedure, the horseshoe-shaped implant is inserted with the cortical end of the implant located posteriorly, which has been reported to increase the fusion rate while decreasing the graft extrusion and collapse sometimes experienced with the Cloward dowels (Whitecloud and Dunsker, 1993). However, in a recent study evaluating the success and relief rates achieved according to these procedures, it was found that less than 100% success rate (fusion, patient improvement and absence of complications) was achieved, regardless of which method or implant was used (Grooms *et al*, 1996).

U.S. Patent No. 5,306,309, discloses a spinal disk implant comprising a solid body of biocompatible synthetic material arranged to define a right-rectangular solid having two opposed side faces and two opposed transverse faces, including a convexly curved anterior face and a posterior face, for implantation in the intervertebral space. The discussion of vertebral and intervertebral morphology is hereby incorporated by reference.

U.S. Patent No. 5,609,635, discloses a lordotic interbody spinal fusion implant comprising a wedge shaped metallic cage for insertion into the intervertebral space.

U.S. Patent No. 5,306,307, discloses a ceramic spinal disk implant having a serrated edge.

None of these references disclose a cortical bone intervertebral implant having a substantially "D"-or bread-loaf-shaped structure having a canal into which osteogenic, osteoinductive, or osteoconductive materials may be packed, which sustains spinal loads, and which is remodeled into the spine in the course of fusion. Accordingly, the present invention addresses the need in the art for improvements to both the implant and the avoidance of post-surgical complications from anterior cervical fusions. The present invention provides a new cortical bone implant for use in achieving anterior cervical fusions when implanted according to the Smith-Robinson procedure. In addition, in view of the peculiar characteristics of bone, the present invention comprises unique methods and apparatuses for the manufacture of the substantially "D"-shaped cortical bone implant.

2.0 Summary of the Invention

An implant composed substantially of cortical bone is provided for use in cervical Smith-Robinson vertebral fusion procedures. According to methods of this invention, the implant is derived from allograft or autograft cortical bone sources, is machined to form a substantially "D"-or other appropriately shaped implant having a canal into which osteogenic, osteoinductive, or osteoconductive material may be packed. The implant is inserted into the space between adjacent cervical vertebrae to provide support and induce fusion of the adjacent vertebrae.

3.0 Brief Description of the Drawings

Figure 1 provides several views of the fusion implant of this invention.

Figure 2 provides views of the core cutter and drill assembly and the bone plug formed by cutting into the diaphysis of a long bone when such a core cutter and drill assembly is used.

Figure 3 provides a view of broach as used according to this invention and an asymmetric canal formed by use of such a broach.

Figure 4 provides several views of an apparatus for machining a profile on the exterior surface of the implant of this invention.

Figure 5 provides a view of an apparatus for inscribing retention teeth in the upper surface, lower surface or both upper and lower surfaces of the implant.

Figure 6 provides several views and dimensions for specific embodiments of the implant of this invention.

Figure 7 provides a view of a stacked embodiment of the implant of this invention.

Figure 8 provides several views of an implant of this invention formed by juxtaposition of mirror image halves of the implant, as well as an embodiment useful for posterior lumbar intervertebral fusion procedures (PLIFs).

Figure 9 provides a view of a stacked embodiment of the implant of this invention wherein the stacked constituents thereof are retained in registered relationship by press-fitting or otherwise

bringing more than one implant into contact with each other and having a cancellous plug or other biocompatible material located in the central canal of each stacked implant, thereby acting as a retention pin.

Figure 10 shows an alternate method for producing bone stock for making the implant of this invention of essentially unlimited height from the anterior margin of the tibia or the linea aspera of the femur.

Figure 11 shows dimensions and further processing of the implant of this invention produced according to the alternate method of figure 10.

Figures 12-17 show final profiles for implants produced according to the alternate method of figures 10 and 11.

4.0 Detailed Description of the Invention

According to this invention, a substantially "D"-shaped cortical bone implant for cervical Smith-Robinson fusions is produced, preferably under aseptic conditions. Class 10 clean room processing is desirable, and sterilization of all machining tools is likewise preferred, (particularly after switching from one allograft donor to the next), so that the finished product may be treated by standard techniques known in the art (alcohol, peroxide, or like treatments), prior to storage and shipment to physicians for use in implantation procedures. Because of the peculiarities of working with bone, and in particular, because of the desirability of maintaining aseptic conditions while working with this material, novel approaches have been adopted in the production of the product of this invention.

The implant is preferably formed from cortical bone obtained from tibia, femur or other source of strong cortical bone. The bone source may be autograft or, due to possible complications at the donor site (infection, pain, delayed healing), is preferably, allograft bone. In addition, it is critical that the source bone be derived from a donor whose medical history is well known (absence of transmissible diseases, cancer, osteoporosis), and that the donor bone be obtained under aseptic

conditions according to accepted practices in the art of tissue banking. In addition, extensive *in vitro* testing should be conducted to ensure the absence of pathogenic agents.

The approach adopted in describing the implant of this invention is to first provide a narrative disclosure of preferred methods for making the implant, followed by a detailed description of the implant itself, followed by a detailed description of various apparatuses and aspects of the machining process, and finally, a detailed description of the method of using the implant.

4.1 Narrative Description of Implant Manufacture

While any shape of cortical bone may be used to begin with, we have found that for consistent production of cortical bone which may be reliably machined, it is advantageous to commence with a plug of bone which extends from the exterior of the diaphysis of a long bone toward the intramedullary canal (where, *in vivo*, the bone marrow resides). The result is a bone plug or dowel which has an outer substantially cortical end and an internal end which is composed largely of soft cancellous bone. In cutting the bone plug, we have discovered that the use of a core cutter is convenient. This device comprises an outer coring element of any desired diameter, whereby the diameter of the bone plug is defined, and a centrally located solid drill bit, which provides a canal through the center of the bone plug as well as stability for the core cutting element. The core cutter-drill assembly is preferably torqued by an air drill, driven by sterile air, and the source bone is preferably immobilized in a sterilized vice during the core-cutting process.

We have discovered that in the above-described manner, cortical bone implants may be fashioned having heights, widths and lengths which are practically useful in the Smith-Robinson cervical fusion method. According to this method, the height of the implant is only limited by the distance from the exterior of the bone diaphysis to the intramedullary canal. However, we have discovered that, by this method, final implant heights from about 7 mm to about 14 mm may be produced, depending on the choice of bone source and the location on the bone from which the bone plug is cored. Since it is extremely rare for the cervical intervertebral space to extend beyond these limits, this method is therefore capable of supplying implants of required or useful heights.

Likewise, the length and width of the implant are defined by the diameter of the core-cutter, and final lengths and widths of between about 7 and 14 mm are easily provided for by this method. In addition, where the need arises for heights between about 10 mm and 14 mm, or if difficulty is experienced in obtaining donor bone having a sufficient width from the exterior of the bone to the intra-medullary canal to provide such heights, alternate methods of producing the implant of desired heights disclosed herein may be employed. For example, in a first such alternate method, implants of this invention are produced and then stacked to provide a unitary implant of the desired height dimensions. Such stacked implants may be maintained in a unitary association by drilling appropriate holes through the height of the implant, and inserting therein appropriate retention pins made from any desirable material, including cortical bone, bioabsorbable synthetic polymer, titanium or other metallic retention pins. Alternatively, the stacked implants may be retained in a unitary association by means of a plug of cancellous bone, hydroxyapatite or other biocompatible, osteoconductive or osteoinductive material, and press-fitting the stacked implants to achieve the desired height (see figure 9). In a further alternate method, a section of cortical bone along the long axis of a long bone may be machined according to methods known in the art. By then further shaping and cutting appropriate heights in such cortical bone, and bringing halves of the implant into juxtaposition with each other, implants of any desired shape and height are produced. In yet a further alternate procedure, (see figures 10-17), unitary implants of this invention of essentially unlimited height are produced by length-wise sectioning the anterior margin of the tibia or linea aspera of the femur, segmenting the substantially triangular cortical bone to desired heights, drilling a cannulation through the segments thus produced, and finally shaping the implants to desired dimensions, as defined below for the first principal method of making the implant of this invention.

Continuing with a description of the first method for making the implant of this invention, the cancellous bone on the internal side of the bone plug is removed by any convenient means, including with a saw, an abrasive means such as a diamond tipped rotary sander, or a tooling bit mounted in a lathe, to produce a "washer" shaped piece of substantially cortical bone. Both the internal and external ends of the bone plug should be machined flat, thereby forming a top face and a bottom face, each of which is substantially planar, and preferably parallel. While the cancellous

bone is partially or completely removed by this process, there remains a slight difference in the density of the bone from the external (cortical) to the internal (cancellous or originally intra-medullary) aspect of the bone plug. It is desirable to record the orientation of the bone plug as subsequent machining steps proceed most efficiently when machined from the external aspect toward the internal aspect.

In order to accommodate subsequent machining steps and to provide an orientation to the implant according to which the surgeon may properly insert the implant, the circular internal canal formed by the centrally located solid drill bit of the core-cutter is modified to form an asymmetric shape, such as a key way. This may be achieved by any of a number of different means, including drilling a slot into an aspect of the internal canal closest to the external (more dense cortical) end of the dowel. In one embodiment of this invention, we have found that an implant of consistently good final quality may be machined by conversion of the circular canal into a substantially "D" shaped canal having three essentially rectangular walls and a fourth convexly curved wall. We have found that it is desirable for the curvature of the convexly curved wall to approximate the external curvature of the bone plug. This modification may be achieved by any of a variety of means. However, we have invented an efficient means by which consistently usable implants may be reproducibly machined. This is accomplished by immobilizing the implant, for example in an arbor press assembly, and, preferably from the originally cortical external (denser) end of the implant, slowly forcing a broach through the originally circular canal. The broach is preferably a hard metallic member having a plurality of spaced-apart ribs or rings machined therein, with indentations provided between each ring which thereby form the spacing between adjacent rings. In addition, the edges of each ring are desirably very precise, angular, and sharp, such that as the broach is forced through the originally circular internal canal, the sharp cutting edge of each ring shaves off an incremental amount of bone as the ring passes through the implant. Each ring of the plurality of rings has a shape which, starting at the insertion end of the broach is tapered from an essentially circular shape to any desired final shape for the canal. Accordingly, in one embodiment of this invention, the rings transition from a circular shape to a substantially "D"-shaped profile or any other desired shape over several inches and over a plurality of spaced apart rings. It will be appreciated

that the length of the broach and the number of rings used is defined by the amount of bone that must be removed to form the new shape, the width of each ring and the width of the space between each ring. Removal of no more than about 0.004" of bone by each ring has been found to be a sufficiently small transition to ensure that the vast majority of implant blanks survive this machining step. Broaches of approximately 6" in length have been found adequate for most implant shapes, but for very asymmetric shapes (e.g. an implant which is 11 mm wide and 14 mm long), more bone would need to be removed to form the "D"-shaped canal than from a symmetric implant (e.g. a 14 mm wide by 14 mm long implant). This need may be accommodated by use of more than one broach, with the shape of the insertion end of each consecutive broach substantially matching the shape of the last ring on the previous broach.

Having formed an asymmetric shape, such as a key way, from the internal canal running through the implant, we have found it desirable to modify the external profile of the implant from a substantially circular shape to another desired form. In one embodiment of this invention, the external form of the implant is machined so as to proportionately match the shape of the substantially "D"-shaped internal canal. An external "D"-shaped profile has been used in implants known in the art (see for example U.S. patent 5,306,309; 5,522,899) made from materials other than bone, because of the ability of the convexly curved face of the implant to substantially match the curvature of the anterior aspect of the intervertebral disk into which the implant is to be inserted, as well as to provide efficient spinal load distribution over the remainder of the implant. However, due to the peculiar nature of bone, and the requirements of aseptic or sterile manufacturing, inventive methods and apparatuses were required to produce the desired external profile for the cortical bone implant. It will be recognized that, based on the instant disclosure, a substantially "D"-shaped external profile of the implant may be machined by a variety of means which vary from the precise methods disclosed herein. In addition, other external profiles than the "D"-shaped profile are likewise enabled by modifications of the methods and apparatuses disclosed herein for formation of the "D"-shaped external or internal profile. Thus, according to one alternate method of making the implant of this invention, for example where the linea aspera of the femur is sectioned or where the

anterior margin of the tibia is sectioned, an external profile that substantially varies from a "D"-shaped device may be produced, (see figures 10-17).

We have found it convenient and reproducible to use either of two principal methods for machining the external profile. The implant, with the "D" or alternately shaped internal canal being used as a key way, is fitted onto the end of a spindle which precisely matches the shape of the internal canal of the implant, thereby providing purchase for machining of the external profile of the implant. In a first preferred method, as the implant is rotated on the spindle, it is contacted with an asymmetric generator (grinding) wheel attached to a cog which meshes at a known registration point with a cog to which the spindle with the implant is attached. The speed of rotation of the exterior of the spindle mounted implant, and the exterior of the generator wheels are designed to differ such that as the generator wheel and implant are contacted and are rotated in fixed registration, the generator surface (which is preferably an abrasive diamond plated surface), grinds bone from the external surface of the implant, to form a profile thereon defined by the asymmetric shape of the grinder wheel.

In a second external profile generation method, the implant, with the "D" or alternately shaped internal canal being used as a key way, is fitted onto the end of a spindle which precisely matches the shape of the internal canal of the implant, thereby providing purchase for machining of the external profile of the implant. In this method, the spindle is affixed to an asymmetric cam which rotates concentrically with the spindle, and therefore the implant. The thus mounted implant is contacted with a cutter means, such as a sharp bit having cutting edges which rotate about an adjacent axis. The implant mounted spindle riding on the asymmetric cam is biased to contact the rotating cutter, which thus traces a profile onto the exterior of the implant defined by the shape of the asymmetric cam. For purposes of this disclosure, use of the term "asymmetric cam" should be understood to mean any desirable shape such that upon production of the implant, the shape thereof is defined by that of the asymmetric cam. Shapes contemplated by this disclosure include, but are not limited to, elliptical shapes, D-shapes, partially curved shapes, and the like. The implants produced according to any of the alternate procedures are likewise shaped, although the final shape

may vary depending on the size of the bone stock used (see for example the final shapes of the device shown in figures 12-17).

Once the external profile has been machined, the implant is removed from the spindle, and the machining of the implant may either be terminated, to provide a substantially "D"-shaped cortical bone implant with flat upper and lower surfaces, or an external feature may be machined into the upper and lower surfaces to prevent backing out of the implant upon insertion into the intervertebral space. This may be achieved by a number of means, such as by machining annular rings, indentations and projections, ribbing or teeth into the upper, lower, or both surfaces of the implant. In a preferred embodiment of this invention, the implant is passed through a set of opposing jaws bearing teeth which broach a tooth-shaped profile into the implant as it is forced through the jaws. Alternatively, the implant is passed several times over a ridged surface which cuts the desired tooth profile into the upper, lower or both surfaces of the implant. Preferably, the thus formed teeth angle toward the anterior (convexly curved) face of the implant to prevent backing out of the implant once it is inserted into an appropriately shaped cavity formed in the intervertebral space in an anterior aspect of the cervical spine. In order to accommodate the difficulty surgeons experience in forming precise angles when forming such cavities in the spine, (see for example U.S. patent No. 5,397,364 disclosing a beveled edge to reduce trauma upon insertion of a metallic spinal implant), a beveled edge of defined radius is preferably machined into three faces of the implant, but leaving the anterior face unbeveled. The sharp anterior edge, like the teeth in the upper and lower surfaces of the implant, retards backing out of the implant.

4.2 Detailed Description of the Implant

Referring now to figure 1A, there is shown a top view, as if viewed from the top of the spinal column, of a substantially "D"-shaped cortical bone implant **100**. The implant has a wall thickness **101**, a length **103**, a width **102**, and an internal canal **104**, which fall within desired tolerances (see discussion below). The implant comprises four contiguous walls, including a substantially straight rear wall **105**, substantially straight side walls **106** and **107**, and a preferably curved front wall **108**.

In figure 1B, there is shown a side view of the implant **100**, revealing the height **109**, of the implant. In addition, this view shows, in outline, the internal side walls **106'** and **107'** of the internal canal, **104**. It also shows the top **110** and bottom **111** surfaces of the implant. In figure 1C, there is shown a top view of an embodiment of the implant **100** in which an external feature **120** has been inscribed onto the top **110** and bottom **111** surfaces of the implant. In addition, a "radius" or bevel **115** is shown on the two side and posterior edges of the implant. Figure 1D shows a side view of the implant **100** in which the inscribed feature **120** can clearly be seen in the top **110** and bottom **111** surfaces of the implant. In this view, it can be seen that the external feature **120** has the side profile of a set of teeth, all of which angle toward the anterior face **108** of the implant. An outline of the bevel **115** is also evident in this view, as is the rounded posterior edge **105**. As can be seen, in this embodiment of the invention, the anterior edge **108** is maintained with a sharp edged. In figure 1E, there is shown a detail of one embodiment of the inscribed feature **120** on the portion of the implant indicated in figure 1D. In a preferred embodiment, the feature **120** defines a tooth-like structure, with teeth **121** separated from each other by concavities **122**. An angle **θ** defines the grade of the concavity as it ramps to the tooth. The tooth height **123**, space between teeth **124**, and aperture of the concavity **125** may all be defined by the manufacturer to optimize retention of the implant within the cervical spine after proper placement.

<u>4.3 Detailed Description of the Method of Manufacturing the Implant</u>

Because of the peculiar nature of bone, and the desirability of sterile or aseptic manufacturing, specific and specialized procedures and apparatuses are required for successful formation of the implants of this invention. Those skilled in the art will recognize that, based on the methods and apparatuses disclosed herein, the implant of this invention may be manufactured by alternate means suggested by those described herein. Nonetheless, through careful design and knowledge of bone structure, instruments for the manufacture of the implant of this invention have been invented for this purpose. In what follows, specific details with respect to preferred method

and apparatuses for making the implant of this invention are provided. It should be recognized that the invention should not be construed as being limited to these specifics.

Referring to figure 2, there is shown in side view in figure 2A a core cutter **200**, having a core bit **201** which is affixed by a set screw **203** to the shaft **204** of a drill bit **202**, centrally located within and coaxial with the core cutter. In figure 2B, an end-on view of the core cutter **200** is provided showing the set screw **203** in outline. Figure 2C shows a side view of the bone plug **210** which is formed by cutting a plug of bone from the diaphysis of a long bone using the core cutter **200**. At one end, **211**, originally the external cortical surface of the bone shaft, there is a substantially cortical bone surface through which a hole **213** is formed by the central bit **202** of the core cutter **200**. The other end, **212**, is an irregular and bone surface which, *in vivo*, formed part of the wall of the intramedullary canal. Cancellous bone or other microstructure at the end **212** is removed, and both ends are ground, cut or otherwise machined to be substantially flat and parallel, to form the substantially cortical bone plug **210** shown in figure 2D.

Referring to figure 3, there is shown in figure 3A an internal canal profile broaching tool **300**. A plurality of spaced-apart ribs or rings **301** are provided along the length of the broach which taper from a substantially circular shape at the insertion end **302** of the broach, to substantially "D"-shaped rings **303** (or any other desired shape) at the completion end **304** of the broach **300** (intermediate ribs **305** are not shown; rather, the outline of the taper angle is shown). A notch or groove **306** is provided in the broach completion end **304** for releasably affixing the broach into a means, such as a press, for forcing the broach through the implant canal. In figure 3B, there is provided an end-on view of the cancellous bone plug **310** after the broaching procedure is completed. As can be seen, the internal canal **104** has been converted from a circular canal into a substantially "D"-shaped canal. As will be appreciated from this disclosure, any of a number of different asymmetric shapes in the internal canal **104** may be defined by this or analogous means, the principal goal being to provide a purchase (referred to herein as a "key way") within the implant for external machining of the implant. In one embodiment (see figure 9), the canal may be retained as a substantially circular canal, and a slot **904** is machined therein to provide the necessary asymmetry to form a key way.

Having formed a key way within the implant, it is possible to modify the external profile of the implant. In one aspect of this invention, referring to figure 4A, this is conveniently achieved by affixing the implant **410** to the spindle **420** of a lathe **400**. The spindle shaft **440** extends, through bearings (not shown), to a means **450** (such as a handle or a motor) for rotating the spindle. Affixed to the spindle-shaft is a cam **430**, the shape of which defines the ultimate external profile of the implant **410**. The spindle shaft **440** and bearings are mounted in a cross slide **441**, which translates in a first plane, referred to as the "Y-plane". Motion in the Y-plane is limited by contact of the cam **430** with a limiting means **460** such as a cam follower, which remains in register with a carriage **442** which translates along a plane, the "X-plane", transverse to the Y-plane motion of the cross-slide . The cross-slide is mounted in a slide-way **443** of the carriage **442**, which in turn is slideably mounted on the bed **444** of the lathe, such that the carriage **442** is permitted to translate along the X-plane. Travel of the slide **442** along the X-plane is limited by means of a stop screw **470**.

Further detail of this means for generating the external profile of the implant is provided in figure 4B, which provides a side view of one specific embodiment of the implant external profile generator **400**. An air driven turbine within housing **401** provides a source of torque to turn a shaft **402**. A means for cutting or grinding the external surface of the implant **410**, such as an appropriately fashioned cutter or bit having a non-cutting end **403** for fixation to the shaft **402**. Extending from the non-cutting end **403** which has a first diameter, is a cutting surface **404**, having a second, smaller diameter. A "shoulder" **405**, forms a radius extending between the smaller diameter of the cutting surface **404** and the larger diameter of non-cutting surface **403**. The cutting surface **404** is contacted with the implant blank **410**, mounted on spindle **420**, to which, as described above is mounted an asymmetric cam **430**. The thus mounted implant blank **410** is brought into contact with the cutting surface **404**, by virtue of translation in the X-plane of the carriage **442**. The spindle **420**, and thus the asymmetric cam **430** are rotated, manually or by motor driven means, through shaft **440** and handle **450** which are attached concentrically with the cam **430**. Preferably, the asymmetric cam **430** is elastically biased toward a stationary cam follower **460**. In this fashion, after several revolutions of the handle **450**, the shape of the asymmetric cam **430** generates the desired external

profile of the implant **410** riding on the spindle **420**, through contact with the rotating cutting surface **404**.

To ensure that the implant blank is machined only up to the point that the forward edge **411** of the implant approaches but does not contact the "shoulder" **405** on the cutter, a stop screw **470** is provided. The stop screw **470** is set to prevent further advancement of the implant blank **410** by stopping advancement of the carriage **442** when the leading edge **471** of the stop screw comes into contact with a measuring screw **480**. The appropriate setting of the stop screw **470** is achieved at the start of the milling process by first placing the implant **410** between the end **481** of the measuring screw **480** and an anvil **482**, and tightening the measuring screw **480** until it just makes contact with the implant. In this fashion, the measuring screw **480** and anvil **482** essentially form a micrometer, with the gap being defined by the width of the implant. Both the measuring screw **480** and anvil **482** are housed within a measuring slide **483** which, when slid all the way to the left as shown in figure 4B, abuts a rotateable stop cam **490**, retained within the same slide-way as the measuring slide **483** by a retainer **484**. The rotateable stop cam **490** may be set in either of two positions, which produces a difference in the stopping point of the stop screw **470** of approximately 0.06". The significance of this difference is that the first position arrests advancement of the stop screw **470** (and therefore the carriage **442**) just before the implant **410** contacts the radius shoulder **405** of the cutting surface **404**. In the second position, the stop cam **490** allows the stop screw to advance the additional approximately 0.06" to allow contact of the implant **410** with the shoulder **405** of the cutting surface **404** to thereby bevel the edges of the implant **410** that are thus contacted. Accordingly, in the pre-milling setup, the stop cam **490** should be rotated such that the stop screw **470** is forced to stop the extra 0.06", following which a further processing step may be carried out in which the stop cam **490** is rotated to the second position in which the stop screw **470** is allowed to advance this additional approximately 0.06".

In figure 4C, there is provided an end-on, rear view (i.e. looking from the handle **450** toward the spindle 420) of the asymmetric cam **430**, the spindle **420** and the implant **410**. In addition, in this detail view, an additional feature in the asymmetric cam **430** is seen as a diminution in the thickness along three faces **431** of the asymmetric cam **430** which is a relief in the rear of the

asymmetric cam **430**. The significance of this relief **431** is that it restricts the contact of the implant **410** with the shoulder **405** to the extent defined by the relief in the rear of the asymmetric cam **430**. As noted above, in fashioning an implant site in the intervertebral space during a partial discectomy, surgeons are unable to produce perfectly sharp angles. To accommodate this imperfection, to prevent trauma upon insertion of an implant with sharp edges, and to create as tight-fitting an implant as possible, the fashioning of a bevel around the edges of the implant that are inserted into the intervertebral space created by the surgeon is desired. At the same time, in order to prevent backing out of the implant, it may be desirable to retain a sharp anterior implant edge, and therefore the relief in the cam **430** does not extend completely around the cam. Thus, upon completion of the external profile of the implant **410** as described above, the carriage **442** is backed away from the cutter, the stop cam **490** is flipped to its second position allowing advancement of the stop screw **470** the additional approximately 0.06" mentioned above. At the same time, a shot pin **432** is advanced into the relief **431** by means of a shot pin mover **433**, thereby allowing rotation of the cam **430** only to the extent permitted by the shot pin **432** as it rides within the relief **431**. With the shot pin **432** riding in the relief **431**, the "shoulder" **405** contacts the leading edge **411** of the implant blank **410**, thereby rounding three edges of the implant **410**. After machining the leading edge **411** of the implant **410**, the implant is removed from the spindle **420**, turned around, and re-positioned on the spindle **420**, to inscribe the bevel on three edges of the other side of the implant.

In figure 4D, a frontal view is provided of the spindle **420**, the implant **410**, the asymmetric cam **430**, and the cam follower **460**. Also shown is the cam adapter **461**, by means of which the cam follower **460** is affixed to the carriage **442**, and by means of which the cam follower **460** maintains the cutting surfaces **404/405** in contact with the implant **410** as defined by the shape of the asymmetric cam **430**. Also shown is a part of the cross-slide **441**, which is preferably biased or which may be pushed manually toward the cam follower **460**.

In figure 4E, a side detail view is provided of the stop cam **490**. In this view, a stop cam handle **491** is shown which allows the operator of the implant outside profile generator to fix the stop cam **490** in a first position **A**, and a second position **B**, whereby additional travel of the stop

screw **470**, and thereby advancement of the carriage **442**, is provided in position **B**, of about 0.06" due to the difference in the distances shown for these positions.

By means of the apparatuses and method described above, a cortical bone implant **100** as shown in figure 1 having a substantially "D"-shaped external profile, and a substantially "D"-shaped internal canal is produced. Naturally, based on this disclosure, those skilled in the art will appreciate that other shapes, both for the external profile and internal canal of the implant may be produced. For example, an ellipsoid is produced by the above described methods simply by modification of the shape of the asymmetrically shaped cam **430**, and the internal canal shape may be modified by drilling, routing, or broaching using a broach that tapers to any desired shape. The thus formed implant may be used after machining as described, followed by appropriate cleaning methods known in the art (e.g. bathing in alcohol, peroxide treatment etc.). In addition, however, it may be desirable to inscribe an external feature on the upper surface **110**, the lower surface **111**, or both. Such a feature may take any desirable form, such as annular rings, indentations, projections, ribbing or teeth. In a preferred embodiment, teeth sloping toward the anterior aspect **108** of the implant are inscribed onto the top **110** and bottom **111** surfaces of the implant by forcing the implant through opposed broaches bearing inscribing teeth. Alternatively, the upper **110**, lower **111** or both surfaces in turn may be repeatedly run, manually or by a machine-driven means, over an appropriately fashioned jaw bearing abrasive teeth such that the required profile of teeth are inscribed into the surfaces of the implant. Desirably, the successive teeth of the jaw are incrementally raised in height such that each tooth is only required to remove a small amount of bone (about 0.004" per tooth, to a total depth of 0.015"). In addition, it is preferred that the rake (angle of the teeth) be sufficiently sharp as to allow the implant to bite into the implantation site, without at the same time being so sharp as to be excessively brittle.

In figure 5, figure 5A, there is provided a top view of one side of one embodiment of blades **502** for use in a broach assembly **500** for inscribing teeth into the top **110**, bottom **111** or both surfaces of the implant. In outline, there is shown a lock-down handle **501** for clamping the assembly of blades **502** to a base **503**. By bringing a mirror image jaw into register with the depicted broach, a space is formed between the opposing teeth **502** at a distance sufficient to accommodate

passage of the implant therebetween, provided that the teeth abrade recesses into the top and bottom surfaces of the implant **100**. To ensure proper engagement of the blades **502** and the implant **100**, there is provided a non-cutting surface **506** for contacting the implant **100** as it is introduced into the broach assembly **500**. The non-cutting surface **506** acts as a type of micrometer, forcing the cutting surfaces of the teeth **502** sufficiently apart to properly engage the implant as it passes through the broach assembly **500**. In figure 5B, there is provided a side view of an implant mounting device **504** having a "D"-shaped cavity **505** into which a "D"-shaped implant may be fitted for passage through the opposing jaws of the broaching jaw apparatus **500**. The resultant implant has the profile shown in figures 1C-1E.

In figures 5C-5E, there is shown an alternate apparatus and method for fashioning the retention teeth in the implant. In figure 5C, there is shown a carriage **510** having an appropriately dimensioned slot **520** for receiving the implant to be grooved. A tensioning screw **530** brings a retention arm **531** into juxtaposition with carriage housing member **532**, thereby clamping the implant into position within slot **520**. Through carriage housing members **532** and **533**, there is aligned a guide-rod **534** for guiding the carriage containing the implant as it is raked across a blade assembly **540**, over which said carriage **510** is made to pass. Said guide rod **540** also conveniently acts as a hinge, allowing the carriage **510** to swing upward for implant loading and also permitting the carriage to move down toward the base as the implant surface is cut on each successive pass of the carriage over said blade assembly **540**. The blade assembly **540** is bolted within a base **550** over which said carriage **510** slides. Said base **550** also acts to receive fixation screws **551** and **552** which retain said guide rod **534** in place. A plurality of individual blades **560** are placed in a recess **554** in the base **550** and are maintained in registered position by retention screws **552** passing through retention holes **553** in each blade. Each blade **560** has an initial non-cutting surface **561**, which is approximately 0.015" below the cutting surface **562**, which in combination with said plurality of blades, forms a flat loading area for implant insertion into said slot **520**. Figure 5D provides a side view of one blade **560**, while figure 5E provides an end on view of the carriage **510** as it sits above the base **550**. Accordingly, the implant is inserted into the slot **520** with the carriage **510** swung up from the base **550**. The carriage is then swung down into the starting position with the implant

making contact with the non-cutting surfaces **561** of the plurality of blades. The implant is depressed so that it is forced snugly against the non-cutting surface, and then tensioned into place with the retention screw **530**. Thereafter, the carriage is slid several times over the base **550** such that the cutting surfaces **562** of the plurality of blades thereby inscribe the desired tooth structure into the top surface, the bottom surfaces or both (after switching the implant around) surfaces of the implant. When the metallic bottom of the carriage comes into contact with the base, the machining of the implant is complete.

In figure 6A-I, there is provided a view of three different cortical bone implants according to this invention having particular geometries by way of example and not limitation. In figure 6A, there is shown an example of an implant **600** which has a height of 7 mm, a width of 11 mm, and a length of 14 mm. In addition, dimensions of various radii of the implant are provided. Note the effect of the "shoulder" **405** of the cutter which produces the a 0.059" radius and indent profile **610** starting at the approximate center of the part and proceeding around to the opposite side of the implant, i.e. around three faces of the implant. In figure 6B, the implant **600** is shown as a side view, and in figure 6C, there is shown a detail view of the teeth. Identical descriptions apply to the 7mmX11mmx11mm views of the implants of figures 6D-6F and the 7mmX14mmx14mm implant of figures 6G-6I.

In figure 7, there is shown a further aspect of this invention in which an implant, either machined as described above, or prior to said machining, is further machined so as to allow stacking thereof to achieve implants of various heights. Commencing from a blank cortical plug at the stage shown in figure 2D has the advantage that if breakage of the implant occurs during machining, this will likely occur prior to completion of all of machining steps. According to this embodiment of the invention, two implant blanks of known height are selected such that a unitary implant composed of both starting implants can be produced of a new desired height (e.g. a 6 mm high implant may be stacked with a 7 mm high implant to produce a 13 mm implant). Each implant blank is placed in a drill jig, and by means of a drill press or like means, holes are drilled through the implants. With the implants still in the jig, the jig is placed on the table of an arbor press. Pins, composed of cortical bone, resorbable but strong biocompatible synthetic material, or metallic pins of the appropriate

diameter are then impelled into the holes in the implants such that the implants are formed into a unitary body by these pins. In order to encourage bony ingrowth, channels may be cut into the adjacent surfaces of the implants. The embodiment shown in figure 7A is a top view of an implant **700** into which four holes **701-704** have been drilled. In figure 7B, there is shown the juxtaposition of two implants **700A** and **700B**, with the drilled holes **701-704** in register to receive pins for maintaining the implants in register. In this view, the adjacent surfaces **710A** and **710B** have not been inscribed with teeth, while the surfaces **711A** and **711B** have been so inscribed. Based on this disclosure, those skilled in the art will recognize that a number of variations and modifications may be made to stack various forms of bone implants, or to maintain such implants in register with each other. These modifications are to be considered within the scope of this invention. Thus, as shown in figure 9, an implant **900** is produced by producing two implants **901** and **902**, each having a cavity or canal **903**, including an asymmetric key way **904** machined therein. By press-fitting the two implants together using an appropriately shaped cancellous plug **905** or a plug made from another biocompatible material, including but not limited to hydroxyapatite, cortical bone, synthetic materials, ceramic, optionally treated with growth factors such as bone morphogenetic protein and the like, the two implants **901** and **902** are retained in registered juxtaposition to form the implant **900**.

In a further embodiment of this invention, shown in figure 8, a method for assembling the implant of this invention from component parts is provided. In figure 8A, there is shown an implant **800** composed of two side-by-side halves, **801A** and **801B**. The two halves of the implant are brought into juxtaposition to form a unitary implant. The two halves may be implanted in juxtaposition, or holes may be formed in each half, and the halves maintained in contact by forcing pins through the holes, in a fashion analogous to that described above for maintaining stacked implants in contact with each other. For this embodiment of the invention, a portion of cortical bone may be harvested from any suitable source of cortical bone. As shown in figure 8B, a segment, in the form of a block or a column of cortical bone is harvested along the long axis of a long bone, such as the femur, tibia, or fibula. The shape of the bone may be inscribed into the thus-harvested cortical bone by routing, broaching or other means as described herein. The thus-machined cortical bone

may then be sectioned into appropriate heights, as needed, to provide the implant halves **801A** and **801B**. Alternate sites for harvesting the cortical bone segment are shown in figures 8B and 8C.

In addition to use for cervical Smith-Robinson type fusion, implants comprising each element, **801A** or **801B** alone, modifications and variations thereof, optionally in combination with another vertebral fusion implant, may be implanted, for example, to assist in induction of posterior lumbar intervertebral fusion (PLIF). In such a case, a device **810**, such as that shown in figure 8D-8G is machined from bone stock as shown in figures 8B, 8C or another appropriate bone stock, and is inserted, according to methods known in the art for insertion of PLIF implants. Preferably, the device as used for PLIF applications has the following dimensions similar to the following, see side view figure 8D:a width **811** of approximately 7 to 12 mm, and preferably about 9.4 to about 10 mm; a top dimension **812** of about 4 to 5 mm; a bottom dimension **813** of about 4-6 mm and preferably about 5 mm; a flat surface of **814** of about 4-7 mm, and preferably about 5.5 mm; a width **815** of about 5-7 mm and preferably about 5 mm; a curvature that defines an angle **816** of between about 60 and 75 degrees, and preferably about 67 degrees. See figure 8E, rear view: a length **L** of about 20 to 26 mm; a height **H** of between about 7.5 and 14.5 mm; preferably, heights of about 8, 10, 12, and 14 mm are produced with lengths of about 20 and 26 mm; desirably, the side faces **817** are machined to display a rough, ridged or grooved surface so that when the anterior end **818** of the PLIF implant is properly seated in place, ridges directed to the posterior end **819** of the PLIF implant prevent backing out of the implant. A detail of one embodiment of such a ridged surface is shown in figure 8F, wherein the following dimensions are preferred: an angle **820** for each tooth of between about 30 and 40 degrees, preferably about 35 degrees; a distance between tooth crests **821** of about 1-2 mm, preferably about 1.5 mm; a tooth crest width **822** of about 0.1 to about 0.2 mm, preferably about 0.125 mm; and a tooth height **823** of between about 0.1 to about 1 mm and preferably about 0.5 mm; returning to figure 8E, the implant preferably has an anterior end width **824** of about 7-13 mm, preferably about 9-13 mm, with a taper angle **825** from the height **H** of about 30 to 40 degrees, preferably about 35 degrees; an instrument attachment means, **826**, such as a tapped instrument attachment hole, is provided in the posterior face of the PLIF implant; this feature is best seen from the posterior view 8G, which shows: an instrument attachment hole **826** having a diameter of about

1.5 to about 2.5 mm, preferably about 2 mm, and a depth of about 4-5 mm, preferably about 4.5 mm; an edge to center of the instrument attachment hole dimension **827** is carefully defined to match dimensions of any implant insertion device used in combination with this embodiment of the PLIF implant; a center of the instrument attachment hole to edge dimension **828** is about 4-6 mm, preferably about 5 mm, with a ridge **829** of about 1 mm running along three edges of the posterior face of the implant. In displaying the section A-A from figure 8D in figure 8E, a slight air gap **830** is shown as the section would exit bone on the concave surface of the implant and then reenter bone.

In use, the implant **810** is inserted on either side of lumbar intervertebral spaces to thereby stabilize and assist in fusion of adjacent lumbar vertebrae. This is accomplished by distraction of the lumbar vertebrae, removal of an appropriate amount and shape of intervertebral disc matter, and insertion of the implant **810**, preferably on each side on a posterior approach, according to methods known in the art. The concave surface of each implant **810** is set to face inwardly, toward the center of the vertebral body, while the convex surface of the implant **810** is set to match, as much as possible, the natural external curvature of the lumbar vertebrae.

In an analogous but alternate method for production of the cervical implant, unitary implants may be produced by appropriately sectioning and machining the anterior margin of the tibia or linea aspera of the femur. Thus, as shown in figure 10A, a left femur **1000** (posterior aspect), or in figure 10B, a left tibia **1001** (anterior aspect), is sectioned at **1004** and **1005** to remove the head, neck and greater trochanter **1002** and internal and internal condyles **1006** of the femur, or tubercle and tuberosity **1003** malleolus **1007** of the tibia. The result from such sectioning is the production of a shaft, or diaphysis, of the femur **1008** or tibia **1009**. Further processing according to this aspect of the invention involves the line asper **1010** of the femur or the anterior margin of the tibia **1011**, as shown in figure 10C. Whether produced from the femur or tibia, a diaphysial shaft **1012**, extending as shown at **1016** to a length permitted by the length of the shaft produced by the sectioning at **1004/1005**. The shaft comprises the natural intramedullary canal **1013**. The thus produced shaft is then further sectioned in a plane shown at **1014** to produce a shaft of bone removed from the natural intramedullary canal **1013** having a cylindrical but somewhat triangular external shape. Into this shaft may be drilled a cannulation **1015**, as shown in figure 11.

Figure 11 shows the substantially triangular shaft of substantially cortical bone **1017** produced by sectioning the shaft of the long bone down the plane **1014**. Into the shaft of bone **1017** may be drilled a bore to produce a cannulation **1015** of appropriate dimensions. The cannulation **1015** may be introduced into the unitary shaft of bone **1017** or it may be introduced into sub-segments thereof by first cutting the shaft **1017** at **1035**. In either case, the diameter of the cannulation **1015** should be limited such that at the narrowest portion between the cannulation and the wall of the device **1020** never falls below about 2 mm. When sectioned at **1035**, for example by mounting the shaft **1017** on a lathe and contacting the spinning shaft with a very narrow blade (i.e. a parting tool of about 1 mm or less width), implant blanks **1030** and **1040** are produced which may be further machined to achieve desired external and internal profiles and key way features, as described for the implant of this invention produced by alternate methods described hereinabove. Implants of any desired height, for example 5 mm to about 14 mm, may thus be produced. Figures 12-17 show specific embodiments of the implant of this invention produced according to this aspect of the invention.

Per figures 12-17, there is provided views of five different cortical bone implants according to this invention having particular geometries by way of example and not limitation. In each figure, view A is a top view, view B is a side view, view C is a detail of the grooves which angle toward the posterior aspect of the implant, and view D is a sectional view through the line A-A shown in view A. In addition, where an osteogenic plug, such as a cancellous plug is present, this is shown in view E as a top view and view F as a side view of the cancellous plug. In figure 12, there is shown an example of an implant having a height **H1** between about 5mm and about 9mm, a width **W1** of about 11 mm, and a width **W2** of about 11 mm. An outer dotted profile provides a means for comparing the shape of the implant produced according to this alternate manufacturing method with the external profile of the implant of figure 6. As can be seen, the implant produced according to this aspect of the invention has a substantially diamond-shaped external profile, as a result of the geometry of the starting shaft **1017** of bone stock.

Figure 13 shows a device similar to that of figure 12, with a cancellous plug inserted therein. Figure 14 shows a device having a width **W1** of about 14 mm and a height **H1** of between about 5

mm and about 14 mm. Figure 15 shows a device similar to that of figure 14 with a cancellous plug inserted therein. Figure 16 shows a device having a width **W1** of about 14 mm, a width **W2** of about 14 mm, and a height of between about 5 mm and 11 mm. Figure 17 shows a device similar to that of figure 16 having a cancellous plug inserted therein. Table I below summarizes the various features and provides examples of specific dimensions for various embodiments of the implant of this invention shown in figures 12-17:

Table I:

		Figure #					
Code	Description	12	13	14	15	16	17
D1	Inner Hole Diameter	5.5	5.5	5.5	5.5	5.5	5.5
D2	Hole Centerline Distance	5.5	5.5	5.5	5.5	5.5	5.5
D3	Key Way Centerline Distance	2.9	2.9	2.9	2.9	4.4	4.4
G1	Groove Depth	0.5	0.5	0.5	0.5	0.5	0.5
G2	Top Flat Width	0.5	0.5	0.5	0.5	0.5	0.5
G3	Groove Pitch width without G5	1.375	1.375	1.375	1.375	1.375	1.375
G4	Groove Pitch width with G5	1.5	1.5	1.5	1.5	1.5	1.5
G5	Flat Width	0.125	0.125	0.125	0.125	0.125	0.125
G6	Groove Angle (degrees)	30	30	30	30	30	30
H1	Overall Height	5-9	5-9	5-13	5-13	5-11	5-11
R1	Keyway Radius	0.8	0.8	0.8	0.8	0.8	0.8
R2	Corner Radius	1.5	1.5	1.5	1.5	1.5	1.5
R3	Outside Arch Radius	11	11	11	11	14	14
W1	Outside Width	11	11	14	14	14	14
W2	Outside Width	11	11	11	11	14	14
W3	Wall Thickness	≥2	≥2	≥2	≥2	≥2	≥2
CP1	Cancellous Plug Height	N/A	5-9	N/A	5-13	N/A	5-11
CP2	Cancellous Plug Diameter	N/A	5.7-5.8	N/A	5.7-5.8	N/A	5.7-5.8

4.4 Manner of Using the Implant

In use, the implant **100** is inserted into a space formed between adjacent vertebrae that are required to be fused. This may be accomplished by the surgeon removing portions of the intervertebral disk, (partial discectomy) and retracting the adjacent vertebrae to allow insertion of an appropriately dimensioned implant. The rear end **105** of the implant is inserted first, and where

present, the external feature **120** prevents backing out of the implant. Where no external feature **120** has been inscribed into the top and bottom surfaces of the implant, it may be necessary to affix the implant in position with plate and screw retention systems known in the art. According to this invention, implants are provided having a height of between about 7 and 14 mm, a length of between about 11 and 14 mm and a width of between about 11 and 14 mm. Any permutation or combination of these dimensions may be envisioned, for example (in order of height, length, width): 7x11x11, 8x11x11, etc.; 7x14x14, 8x14x14, etc.; 7x11x14, 8x11x14, etc.

Preferably, the surgeon performing the implantation saves the autologous material and debris produced in the course of the partial discectomy for packing into the canal of the present implant. In addition, or alternatively, the canal may be packed (either during the surgical procedure or the canal may be pre-packed) with osteogenic, osteoinductive, or osteoconductive materials, including but not limited to: allograft bone, autograft bone, autogenous osteogenic materials including bone marrow cancellous bone and the like, demineralized bone, freeze-dried demineralized bone, Grafton® (demineralized bone in glycerol), bone powder, bone derivatives, bone morphogenetic protein (purified or recombinant), antibiotic, bioactive glass, hyrdorxyapatite, bioactive ceramics, or combinations thereof.

Following implantation, the recipient (whether human or animal) is monitored for implant stability and success in fusion. Fusion is achieved over the course of several weeks to several months, during which time increasing levels of load may be placed on the spine.

5.0 References

Bailey, R.W., and Badgley, L.E. (1960) *Stabilization of the Cervical Spine by Anterior Fusion*, J. Bone and Joint Surg. **42A**:565-594.

Cloward, R. B. (1958) *The Anterior Approach for Removal of Ruptured Cervical Discs*, J. Bone and Joint Surg. **15**:602-617.

Grooms *et al.*, (1996) *Success of Surgery on the Anterior Cervical Spine: Smith-Robinson Technique vs. Internal Plates*, Clinical Performance of Skeletal Prostheses, L.L. Hench and J. Wilson, Eds., Chapman & Hall.

Robinson, R.A., *et al.*, (1962) *The Results of Anterior Interbody Fusion of the Cervical Spine*, J. Bone and Joint Surg. **44A**:1569-1587.

Robinson, R.A. and Smith, G.W. (1955) *Anterolateral Cervical Disc Removal and Interbody Fusion for Cervical Disc Syndrome*, Bull. Johns Hopkins Hosp. **96**:223-224.

Smith, G.W. and Robinson, R.A., (1958), *The Treatment of Certain Cervical-Spine Disorders by Anterior Removal of the Intervertebral Disc and Interbody Fusion*, J. Bone and Joint Surg. **40A**:607-623.

White, A.A. III, and Hirsh, C. (1972) *An Experimental Study of the Immediate Load Bearing Capacity of Some Commonly Used Iliac Bone Grafts*, Acta Orthop. Scandanav. **42**:482-490.

Whitecloud, T.S. III and Dunsker, S. (1993) *Anterior Cervical Spine Surgery, Principles and Techniques in Spine Surgery*, Raven Press, N.Y.

U.S. Patent No. 5,306,309

U.S. Patent No. 5,609,635

U.S. Patent No. 5,306,307

U.S. Patent No. 4,950,296

6.0 What is Claimed is:

1. At least one implant consisting substantially of cortical bone, said implant comprising a canal surrounded by a continuous or discontinuous wall of cortical bone in the shape of a circle, an ellipse, or an asymmetric shape, thereby forming an implant having a top face and a bottom face, each of which is substantially planar, with said planes being substantially parallel to each other.

2. The implant of claim 1 consisting substantially of cortical bone, said implant comprising a canal surrounded by convexly curved anterior cortical bone face and three substantially rectilinear cortical bone faces unitary with said convexly curved anterior cortical bone face.

3. The implant of claim 2 which has a substantially "D"-shaped external profile.

4. The implant of claim 2 wherein said canal has a substantially "D"-shape.

5. The implant of claim 2 further having an external feature on said top face, said bottom face or both.

6. The implant of claim 5 wherein said external feature is at least one groove or tooth.

7. The implant of claim 6 wherein said external feature is a series of teeth which angle toward said convexly curved anterior face.

8. The implant of claim 1 wherein an osteogenic, osteoinductive or osteoconductive composition is packed within said canal.

9. The implant of claim 8 wherein said osteogenic, osteoinductive or osteoconductive composition derives from the intervertebral space into which said implant is inserted, is

hydroxyapatite, bone powder, bone product, bone morphogenetic protein, bioactive glass, bioactive ceramic, or combinations of these.

10. The at least one implant of claim 1 comprising discontinuous walls consisting substantially of cortical bone, wherein said discontinuous walls are mirror image halves which, in combination, form said shape.

11. The at least one implant of claim 1 comprising stacked implants consisting substantially of cortical bone, said implants comprising a canal surrounded by a continuous or discontinuous wall of cortical bone in the shape of a circle, an ellipse, or an asymmetric shape, thereby forming a stacked implant having a top face and a bottom face, each of which is substantially planar, with said planes being substantially parallel to each other.

12. The at least one implant of claim 11 wherein said stacked implants are pinned to each other.

13. An implant consisting substantially of at least two shaped cortical bone implants stacked on top of or adjacent to each other.

14. The implant of claim 13 wherein said shaped cortical bone implants are adapted to form a unitary implant for implantation into an appropriately dimensioned cavity formed between adjacent vertebrae.

15. The implant of claim 14 wherein said cortical bone implants are pinned to each other by cortical bone pins, pins consisting of biocompatible synthetic material or metallic pins.

16. The implant of claim 13 wherein said shaped cortical bone implants are two mirror image halves of a desired shape.

17. A method of making at least one implant consisting substantially of cortical bone, said implant comprising a canal surrounded by a continuous or discontinuous wall of cortical bone in the shape of a circle, an ellipse, or an asymmetric shape, thereby forming an implant having a top face and a bottom face, each of which is substantially planar, with said planes being substantially parallel to each other, said method comprising:

(a) obtaining a plug of bone consisting substantially of cortical bone by using a core cutter having a central drill bit, thereby forming a canal through the bone plug obtained with the core cutter;
(b) machining the bone plug of step (a) to produce a "washer-shaped" bone plug;
(c) machining the canal through the bone plug to form an asymmetric shape therein; and
(d) using said asymmetric shape to machine an outside profile of the bone plug.

18. The method of claim 17 wherein said plug of bone is obtained by cutting into the diaphysis of a long bone and into the intramedullary canal of said long bone to form a bone plug having a substantially cortical end and an end derived from the wall of the intramedullary canal.

19. The method of claim 18 wherein the end of the plug of bone derived from the intramedullary canal is machined to form a substantially planar surface to obtain a substantially "washer-shaped" bone plug composed substantially of cortical bone.

20. The method of claim 19 wherein said canal is formed into an asymmetric shape by broaching said canal to form said asymmetric shape through the bone plug.

21. The method of claim 20 wherein said asymmetric shape is substantially "D"-shaped.

22. The method of claim 20 wherein said bone plug having a substantially "D"-shaped canal is further machined such that the external profile of the bone plug substantially matches the profile of said canal.

23. The method of claim 20 wherein said further machining comprises contacting the bone plug with an asymmetrically shaped grinder wheel.

24. The method of claim 20 wherein said further machining comprises mounting said bone plug on a spindle affixed to an asymmetrically shaped cam and contacting the thus mounted bone plug with a cutter rotating about a symmetric axis such that the cutter is made to cut more or less bone as dictated by the shape of said asymmetric cam.

25. The method of claim 24 further comprising stacking said bone plug, either prior to or after said machining, drilling holes therein, and pining said stacked bone plugs to each other.

26. A method of making at least one implant consisting substantially of cortical bone, said implant comprising a canal surrounded by a continuous or discontinuous wall of cortical bone in the shape of a circle, an ellipse, or an asymmetric shape, thereby forming an implant having a top face and a bottom face, each of which is substantially planar, with said planes being substantially parallel to each other, said method comprising:

(a) cutting a segment of cortical bone;

(b) shaping said segment of cortical bone into a symmetric half of the final shape of said implant comprising a canal surrounded by a continuous or discontinuous wall of cortical bone, such that when implanted in juxtaposition with a mirror image segment, an implant is formed having a circular, an elliptical, or an asymmetric shape, a top face and a bottom face, each of which is substantially planar, with said planes being substantially parallel to each other; and

(c) cutting appropriate lengths of said shaped segment of cortical bone such that said cut length provides half of an implant having a desired height.

27. The method of claim 17 which further comprises machining an external feature into the top the bottom or both surfaces of the implant.

28. The method of claim 27 wherein said external feature is machined by passing said implant through a broach or by repeatedly passing said implant over a plurality of cutting teeth.

29. The method of claim 26 which further comprises machining an external feature into the top the bottom or both surfaces of the implant.

30. The method of claim 27 wherein said external feature is machined by passing said implant through a broach or by repeatedly passing said implant over a plurality of cutting teeth.

31. A broach for forming a canal of desired shape in bone which comprises a plurality of spaced apart rings, wherein the profile of said plurality of spaced apart rings tapers from a first circular ring to a final ring having said desired shape, said taper allowing for removal by each consecutive ring of no more than about 0.004" of bone.

32. An apparatus for forming the external profile of a bone plug having an asymmetric canal, said apparatus comprising (a) a spindle mounted on (b) an asymmetric cam, wherein the shape of said spindle matches the shape of the asymmetric canal of said bone plug so as to allow for a tight mounting of said bone plug onto said spindle, and wherein said asymmetric cam is biased toward (c) a cam follower such that said spindle mounted bone plug is made to contact (d) a cutter means to an extent dictated by the contact of the cam and cam follower such that said cutter fashions an external profile onto the bone plug dictated by the shape of said asymmetric cam.

33. The apparatus of claim 32 comprising:

(a) a cross-slide housing a shaft connected to said spindle, to which is also affixed said asymmetric cam;

(b) a carriage having a slide-way in which said cross-slide translates in a first, Y-plane, said carriage being slideably mounted on a bed such that said carriage translates in a second, X-plane, transverse to said Y-plane;

(c) a cam-follower which limits the translation of said cross-slide in said Y-plane as said asymmetric cam contacts said cam-follower; and

(d) a stop means which limits the translation of said carriage in said X-plane at a first, predetermined location of said cutter means which is maintained in rotating register with said spindle-mounted implant.

34. The apparatus of claim 33 wherein said cutter means has a "shoulder" thereon defining a radius over which the diameter increases from a first diameter of a cutting surface of said cutter means to a second, greater diameter, of a non-cutting surface of said cutter means.

35. The apparatus of claim 34 wherein the advancement of said implant toward the shoulder of said cutter means is limited by said stop, the positioning of which is dictated by a measuring means which is contacted with said implant prior to formation of said external profile, said measuring means dictating the extent of translation of said implant toward said shoulder of said cutter means.

36. The apparatus of claim 35 wherein said measuring means provides a first and a second stop position for translation of said implant toward said shoulder, such the external profile of said implant may be fully defined by said cutter as said implant is translated toward said first stop position in which contact with said shoulder is prevented, and then, a bevel is formed on one or more edges of said implant by permitting contact of said implant with said shoulder of said cutter means as said implant is further advanced toward said second stop position.

37. An apparatus for forming the external profile of a bone plug having an asymmetric canal, said apparatus comprising (a) a spindle, wherein the shape of said spindle matches the shape of said asymmetric canal of said bone plug so as to allow for a tight mounting of said bone plug onto said spindle, and (b) an asymmetrically shaped grinder wheel which may be brought into contact with said bone plug mounted on said spindle, wherein said grinder wheel and said spindle are maintained in registered contact with each other via a gear such that the rate at which the bone plug rotates in relation to the rate of the rotation of the grinder wheel differs sufficiently to allow abrasion of the surface of the bone plug so as to form an external profile thereon which is dictated by the asymmetry of said grinder wheel.

38. A method for inducing fusion of cervical vertebrae which comprises removing a portion of the intervertebral disc between the adjacent vertebrae that are to be fused, and inserting into said space at least one implant consisting substantially of cortical bone, said implant comprising a canal surrounded by a continuous or discontinuous wall of cortical bone in the shape of a circle, an ellipse, or an asymmetric shape, thereby forming an implant having a top face and a bottom face, each of which is substantially planar, with said planes being substantially parallel to each other.

39. The method of claim 38 wherein said canal is surrounded by a convexly curved anterior cortical bone face and three substantially rectilinear cortical bone faces unitary with said convexly curved anterior cortical bone face, thereby forming an implant having a top face and a bottom face.

40. The method of claim 39 wherein said canal is packed with osteogenic, osteoinductive or osteoconductive material.

41. An implant consisting substantially of cortical bone, said implant having been prepared by a process comprising:

(a) obtaining a plug of bone consisting substantially of cortical bone by using a core cutter having a central drill bit, thereby forming a canal through the bone plug obtained with the core cutter;

(b) machining the bone plug of step (a) to produce a "washer-shaped" bone plug;

(c) machining the canal through the bone plug to form an asymmetric shape therein; and

(d) using said asymmetric shape to machine an outside profile of the bone plug.

42. The implant of claim 41 wherein said plug of bone is obtained by cutting into the diaphysis of a long bone and into the intramedullary canal of said long bone to form a bone plug having a substantially cortical end and an end derived from the wall of the intramedullary canal.

43. The implant of claim 42 wherein the end of the plug of bone derived from the intramedullary canal is machined to form a substantially planar surface to obtain a substantially "washer-shaped" bone plug composed substantially of cortical bone.

44. The implant of claim 43 wherein said canal is formed into an asymmetric shape by broaching said canal to form said asymmetric shape through the bone plug.

45. The implant of claim 44 wherein said asymmetric shape is substantially "D"-shaped.

46. The implant of claim 44 wherein said bone plug having a substantially "D"-shaped canal is further machined such that the external profile of the bone plug substantially matches the profile of said canal.

47. The implant of claim 44 wherein said further machining comprises contacting the bone plug with an asymmetrically shaped grinder wheel.

48. The implant of claim 44 wherein said further machining comprises mounting said bone plug on a spindle affixed to an asymmetrically shaped cam and contacting the thus mounted bone plug with a cutter rotating about a symmetric axis such that the cutter is made to cut more or less bone as dictated by the shape of said asymmetric cam.

49. The implant of claim 48 further comprising stacking said bone plug, either prior to or after said machining, drilling holes therein, and pining said stacked bone plugs to each other.

50. An implant prepared by a process comprising:

(a) cutting a segment of cortical bone;

(b) shaping said segment of cortical bone into a symmetric half of the final shape of said implant comprising a canal surrounded by a continuous or discontinuous wall of cortical bone, such that when implanted in juxtaposition with a mirror image segment, an implant is formed having a circular, an elliptical, or an asymmetric shape, a top face and a bottom face, each of which is substantially planar, with said planes being substantially parallel to each other; and

(c) cutting appropriate lengths of said shaped segment of cortical bone such that said cut length provides half of an implant having a desired height.

51. The implant of claim 50 which further comprises machining an external feature into the top the bottom or both surfaces of the implant.

52. The implant of claim 41 which further comprises machining an external feature into the top the bottom or both surfaces of the implant.

53. An apparatus for inscribing an external feature into a bone implant which comprises: (a) a base having a recess, said recess housing (b) a plurality of cutting blades having both a non-cutting upper surface, against which said bone implant may be pressed, and a cutting upper surface,

for inscribing said external feature into said bone implant; said base providing a sliding surface for a (c) carriage; said carriage being slideably fixed to said base by (d) posts holding (e) a guide rod; said carriage further having a (e) tensionable slot for receiving said implant which is loaded into said slot and pushed snugly against said non-cutting upper surface of said plurality of cutting blades, such that said implant may then be raked across said cutting surface of said plurality of blades to inscribe said external feature therein.

54. A method of making a substantially cortical bone implant comprising:

(a) removing the termini of a tibia or femur to produce a diaphysial shaft comprising a natural intra-medullary canal;

(b) longitudinally sectioning the anterior margin of the tibia or linea aspera of the femur as close to the intra-medullary canal as possible to produce a shaft of cortical bone of substantially triangular cross-section;

(c) cutting said shaft of cortical bone into segments of desired length;

(d) drilling a cannulation through a long axis of said segments of cortical bone, wherein said cannulation comprises a bore of such diameter as to leave at least about 2 mm of bone stock between the cannulation and any external side of the cortical bone segment;

(e) machining an asymmetry into the cannulation to produce a key way; and

(f) further machining the cannulated bone segments utilizing said key way as a means for gripping the cannulated bone segments to produce an implant of desired shape and size characteristics.

55. A cortical bone implant produced by the method of claim 54.

56. A method of fusing adjacent vertebrae in need thereof which comprises inserting into a space created between said adjacent vertebrae a cortical bone implant according to claim 55.

57. The cortical bone implant of claim 55 comprising an osteogenic, osteoinductive or osteoconductive material packed within said cannulation.

58. The cortical bone implant of claim 57 wherein said osteogenic, osteoinductive or osteoconductive material comprises a plug of cancellous bone.

7.0 Abstract of the Disclosure

An implant composed substantially of cortical bone is provided for use in cervical Smith-Robinson vertebral fusion procedures. The implant is derived from allograft or autograft cortical bone sources, is machined to form a symmetrically or asymmetrically shaped (e.g. a substantially "D"-shaped) implant having a canal running therethrough according to methods of this invention, and inserted into the space between adjacent cervical vertebrae to provide support and induce fusion of the adjacent vertebrae. Osteogenic, osteoinductive or osteoconductive materials may be packed into the canal of the implant to expedite vertebral fusion and to allow autologous bony ingrowth.

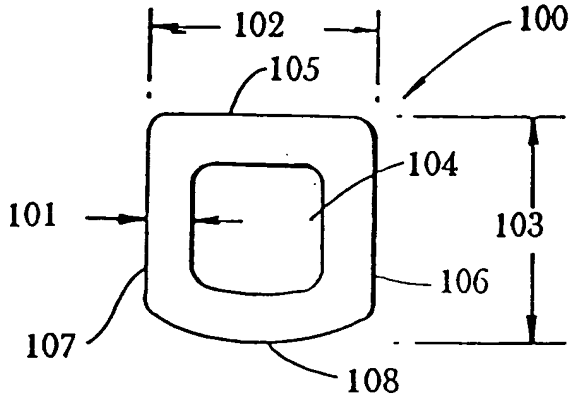


Fig. 1A

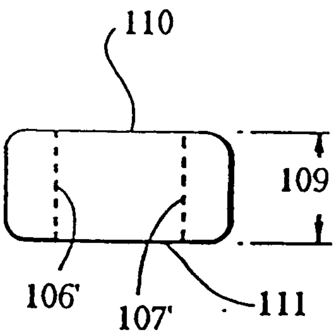


Fig. 1B

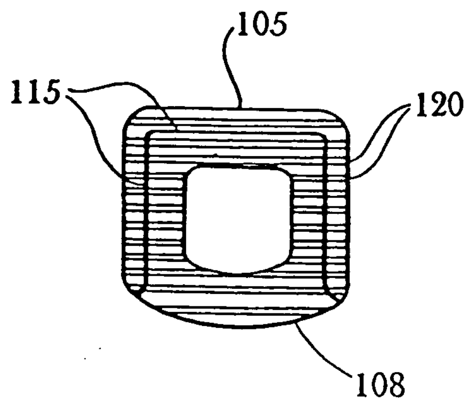


Fig. 1C

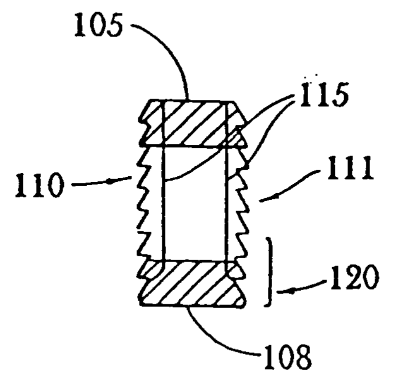


Fig. 1D

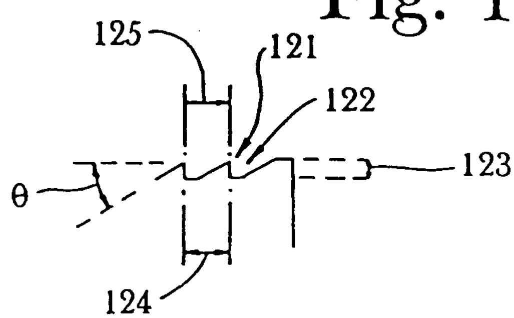


Fig. 1E

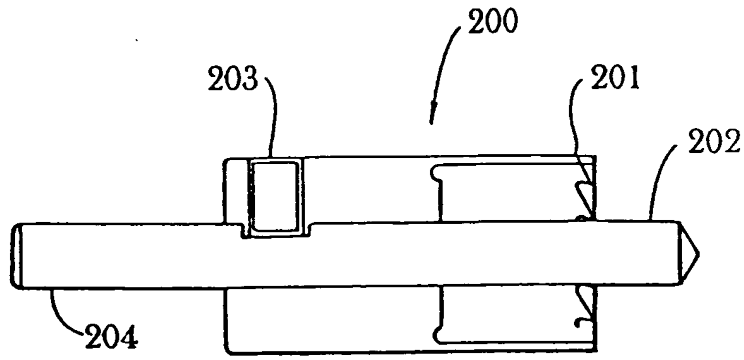


Fig. 2A

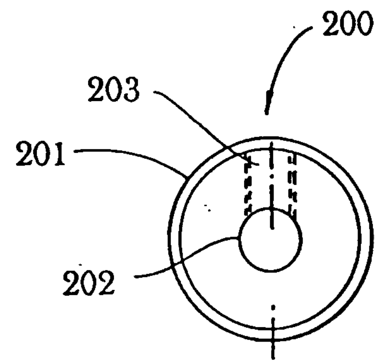


Fig. 2B

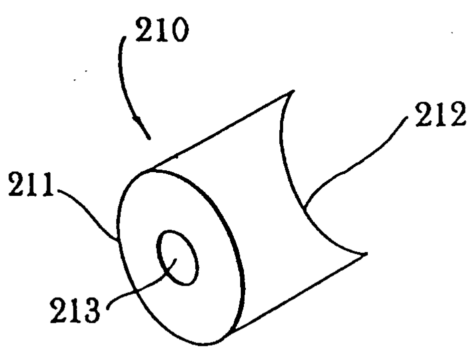


Fig. 2C

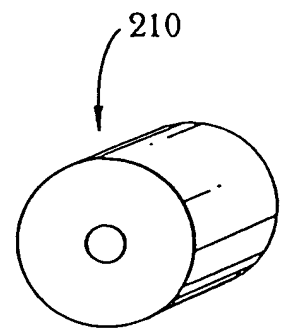


Fig. 2D

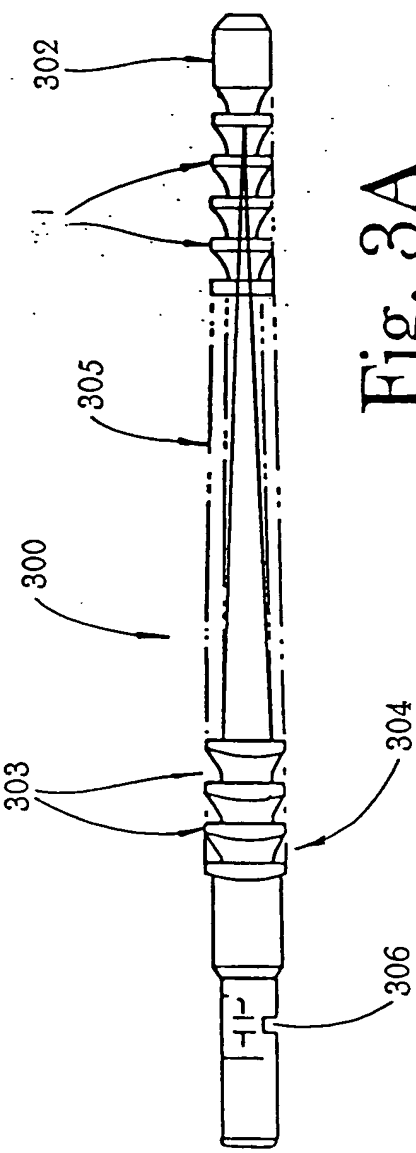


Fig. 3A

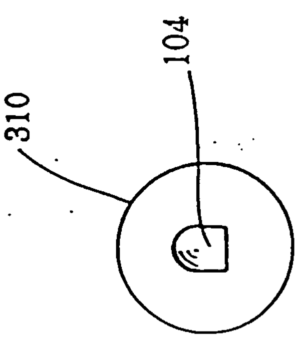


Fig. 3B

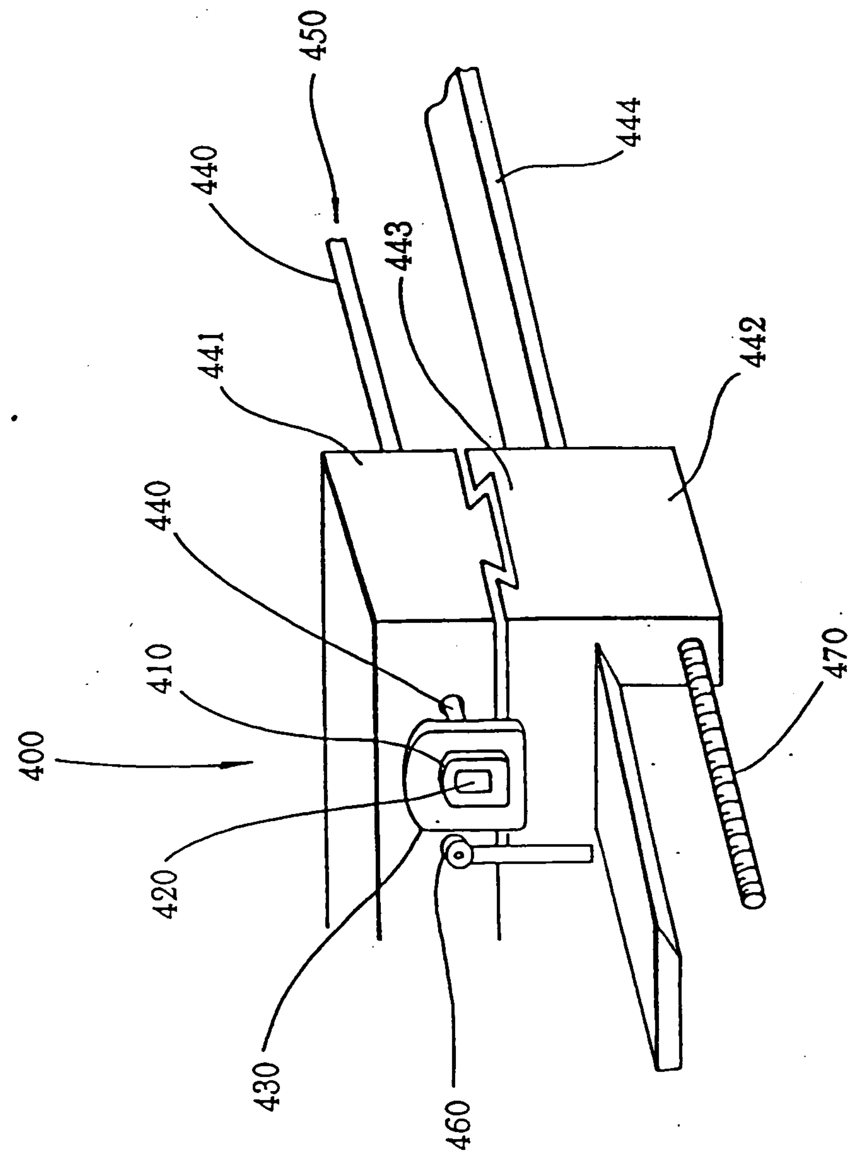


Fig. 4A

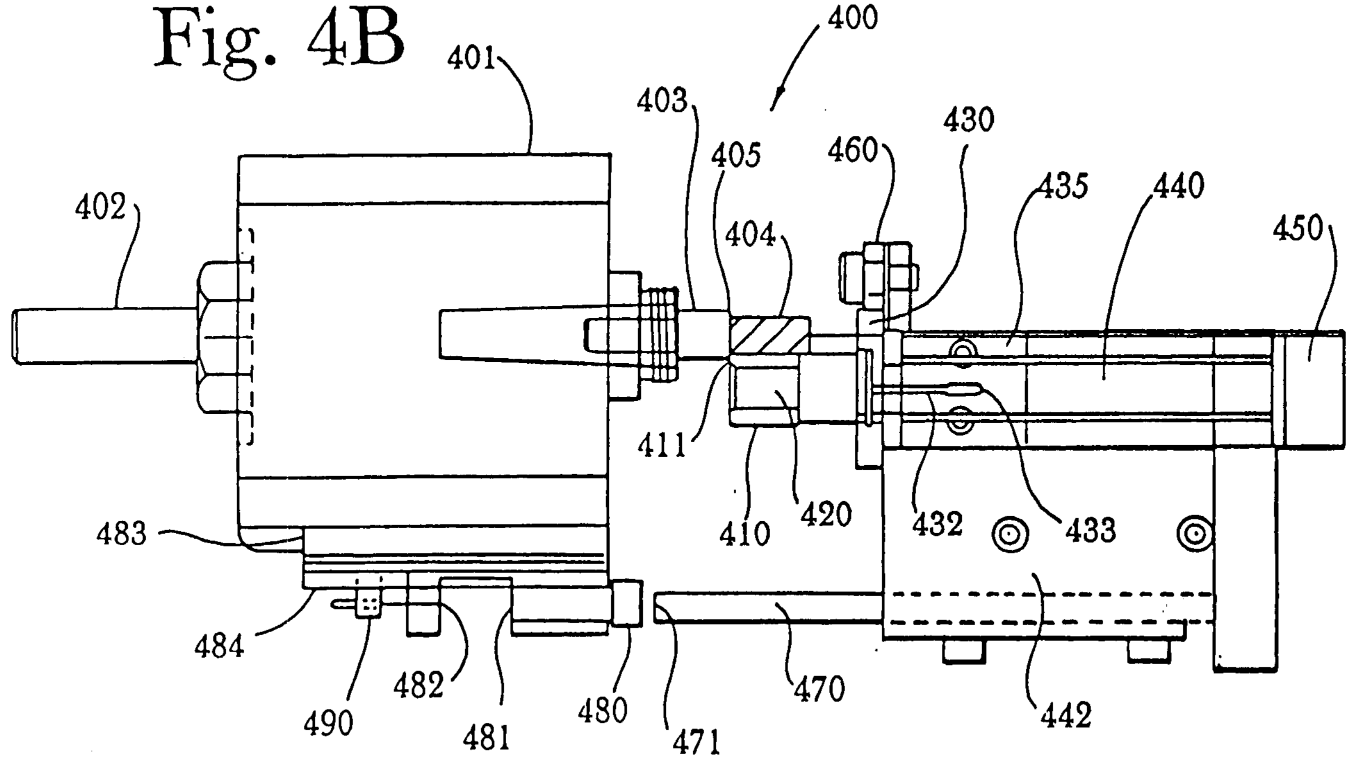


Fig. 4B

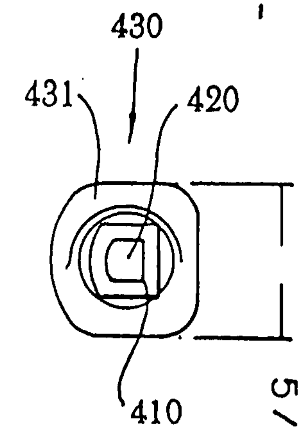


Fig. 4C

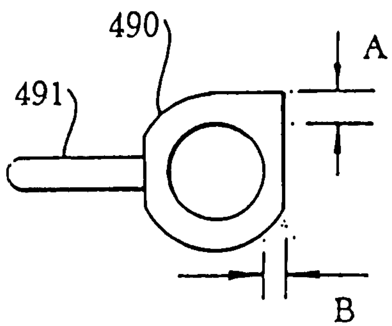


Fig. 4E

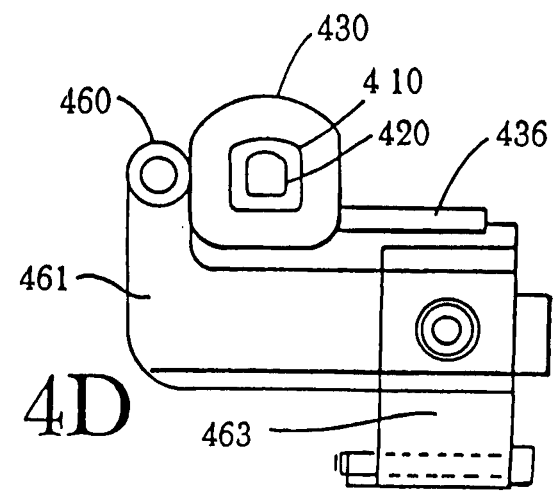


Fig. 4D

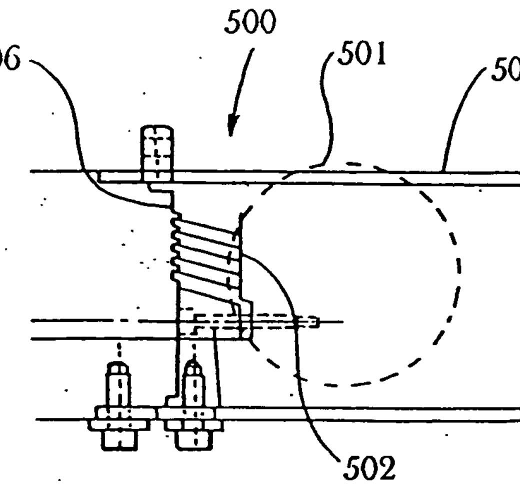


Fig. 5A

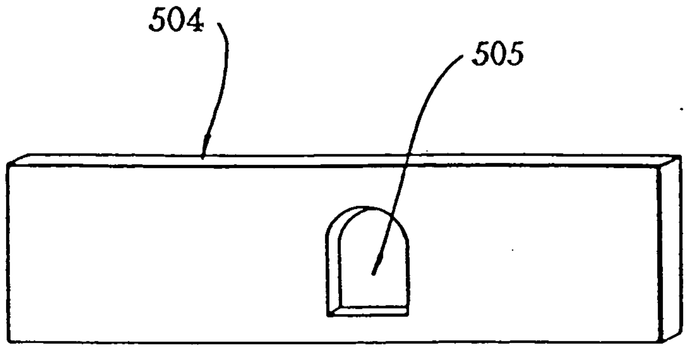


Fig. 5B

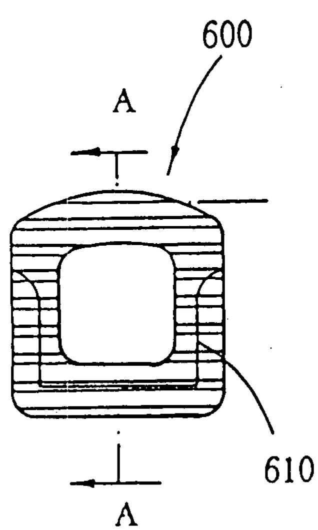


Fig. 6D

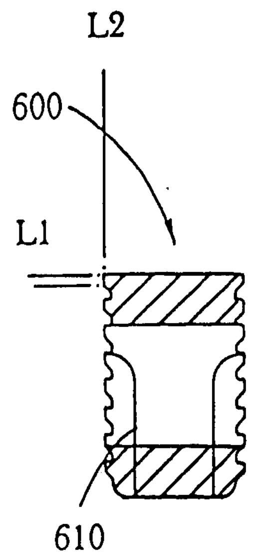


Fig. 6E

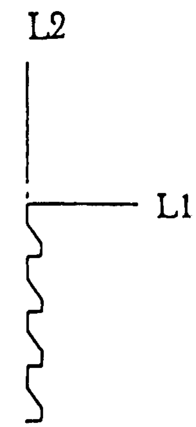


Fig. 6F

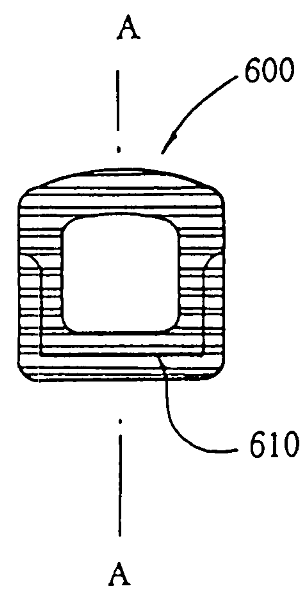


Fig. 6G

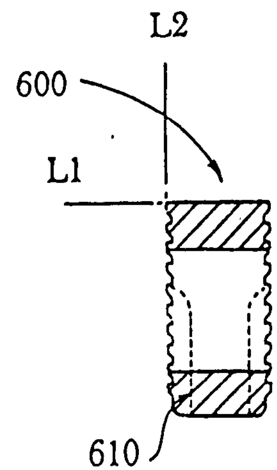


Fig. 6H

Fig. 6I

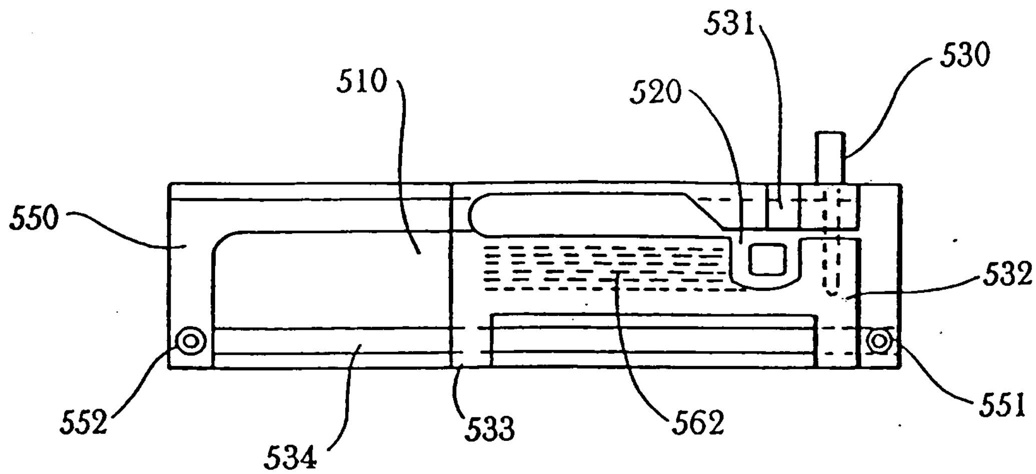


Fig. 5C

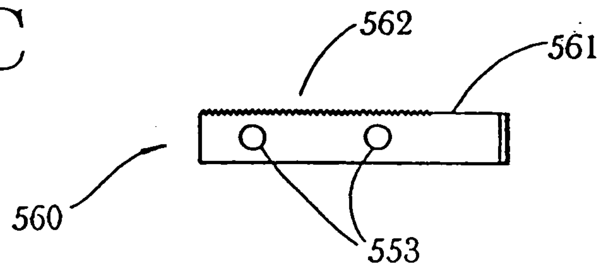


Fig. 5D

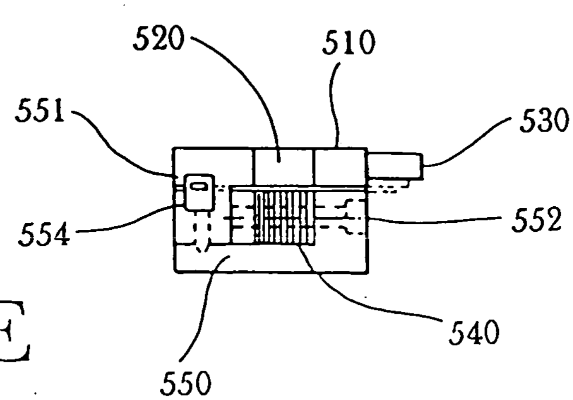


Fig. 5E

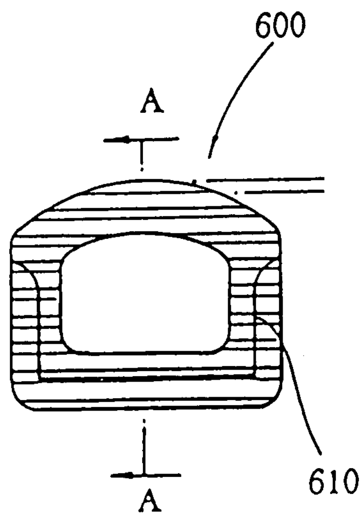


Fig. 6A

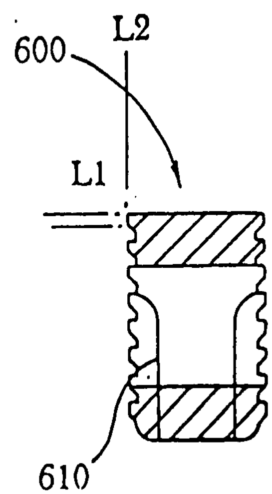


Fig. 6B

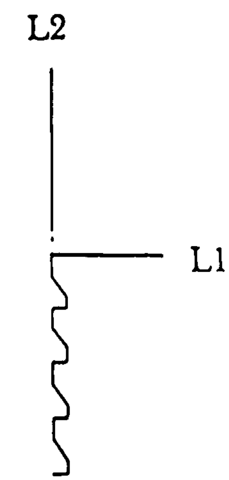


Fig. 6C

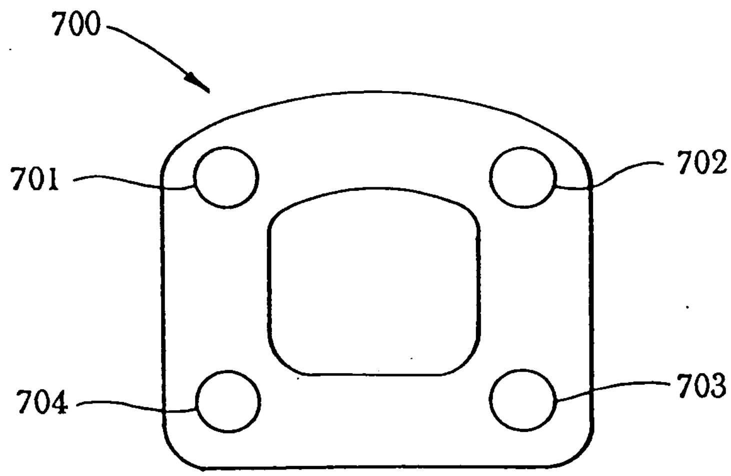


Fig. 7A

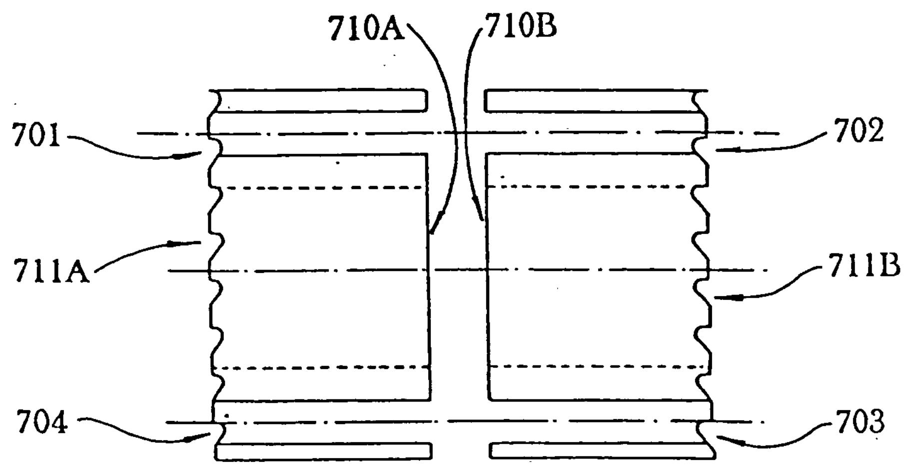


Fig. 7B

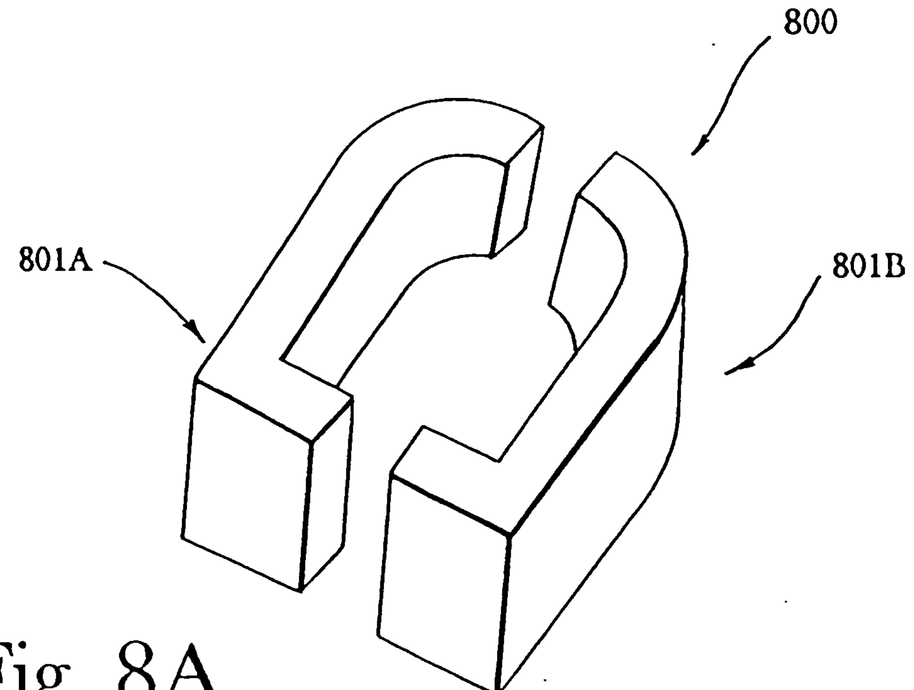


Fig. 8A

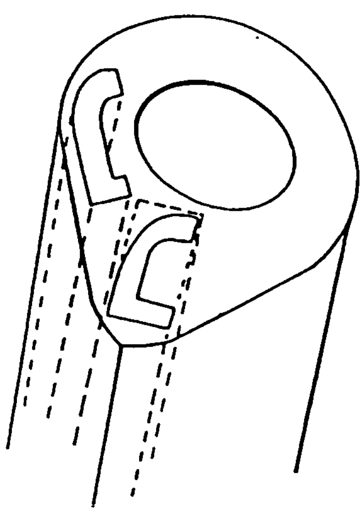


Fig. 8B

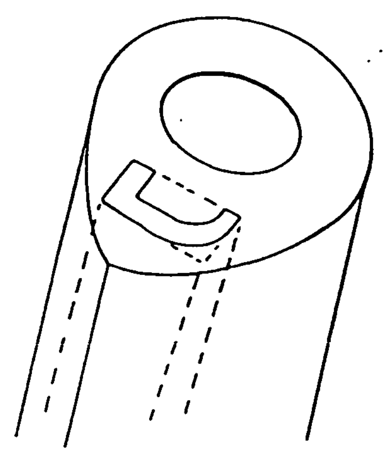


Fig. 8C

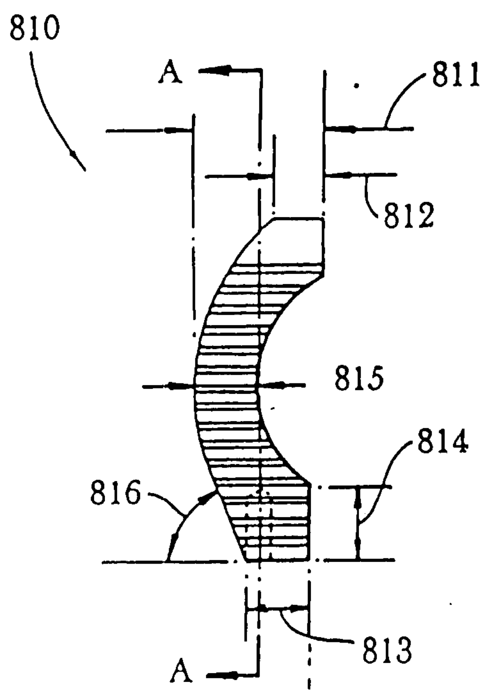


Fig. 8D

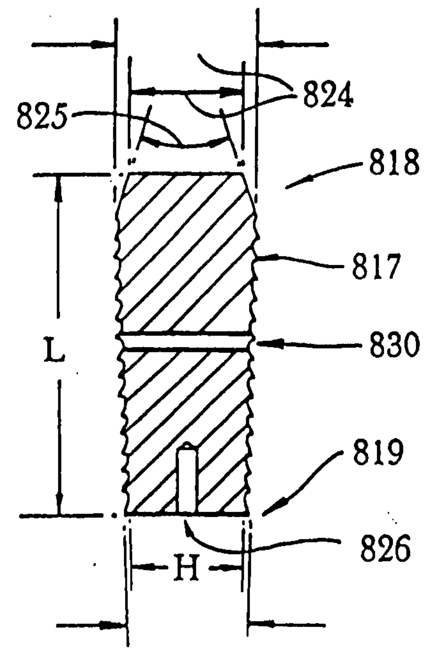


Fig. 8E

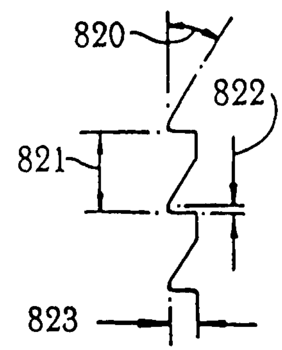


Fig. 8F

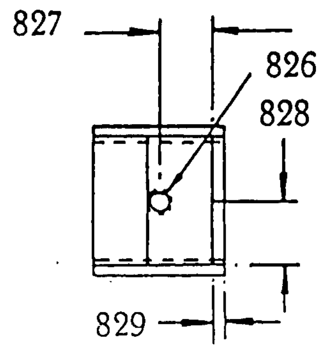


Fig. 8G

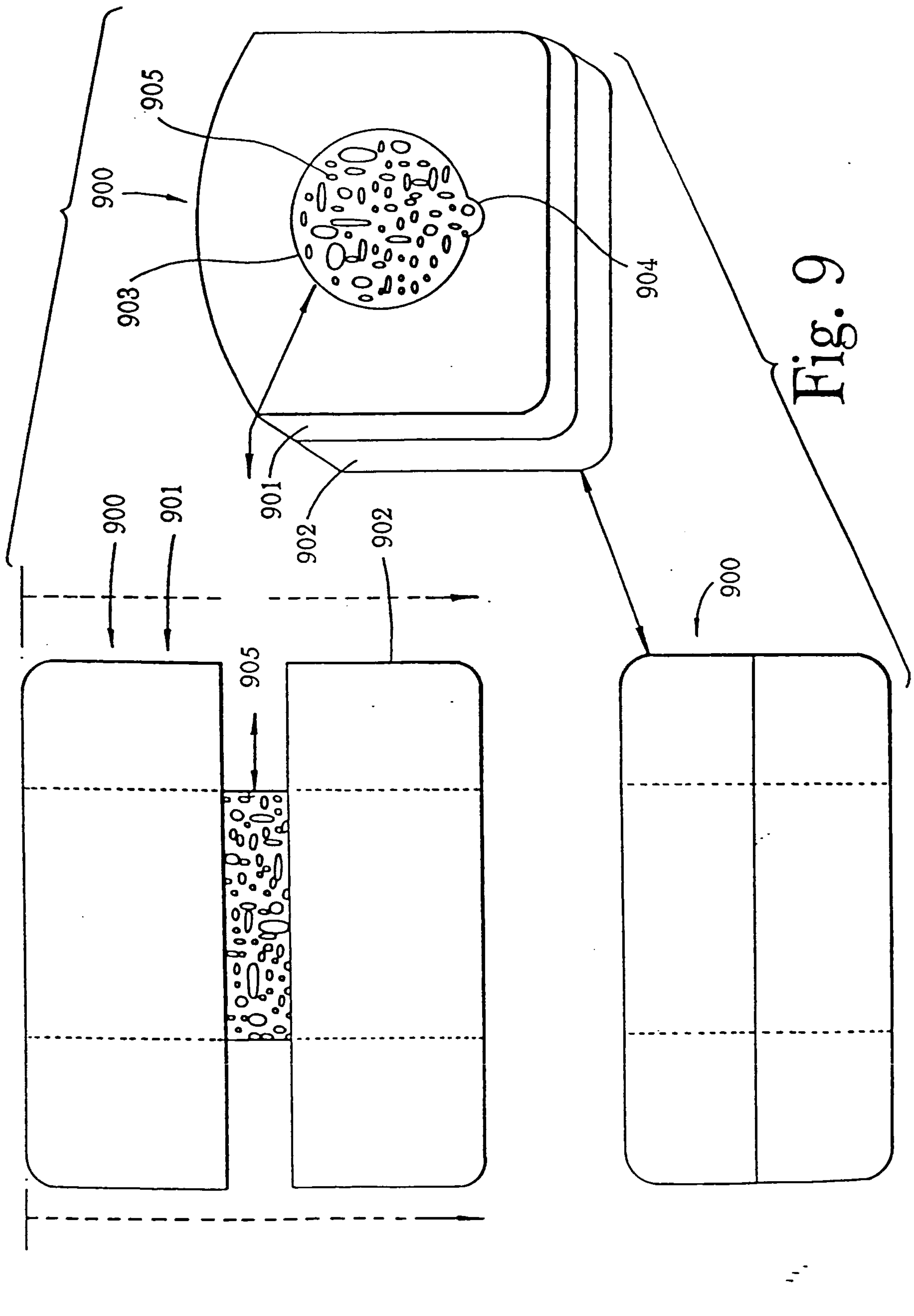
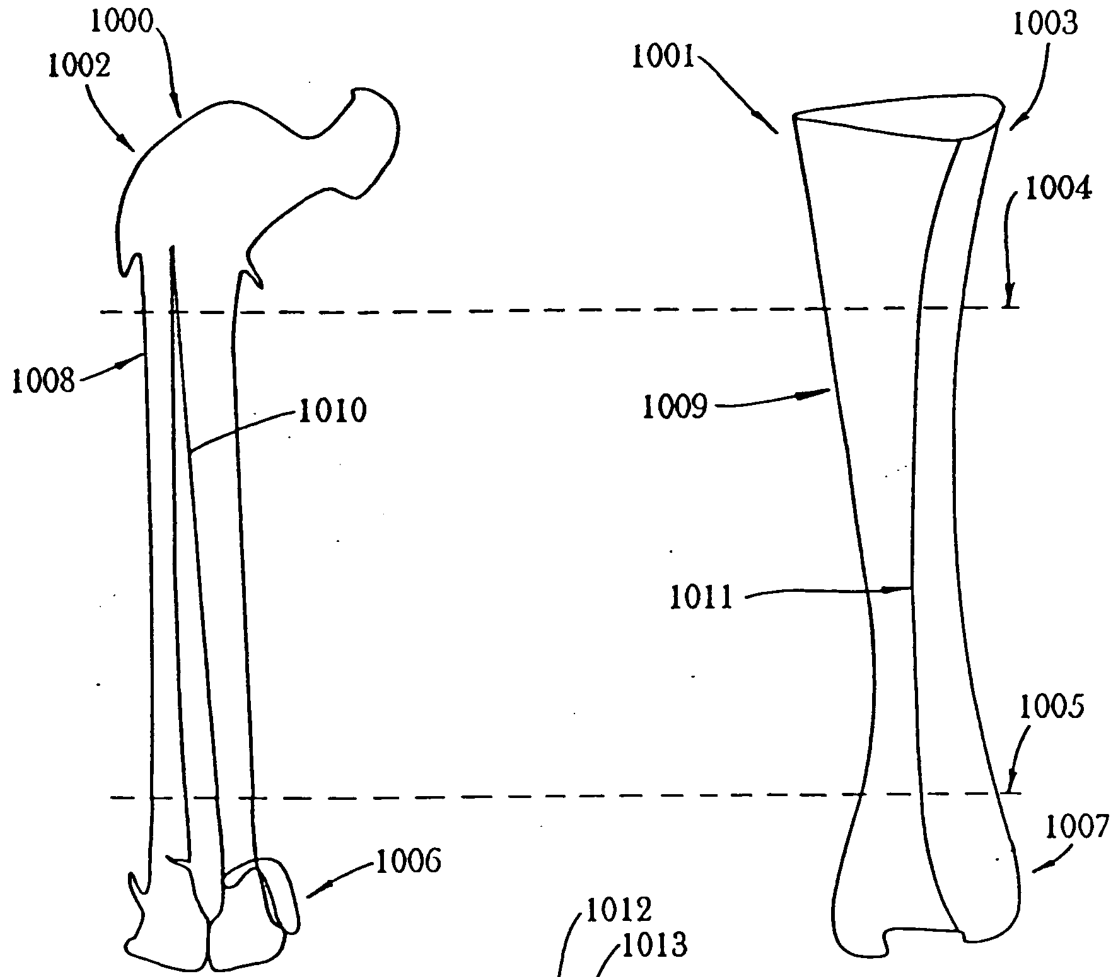


Fig. 9

Fig. 10A

Fig. 10B



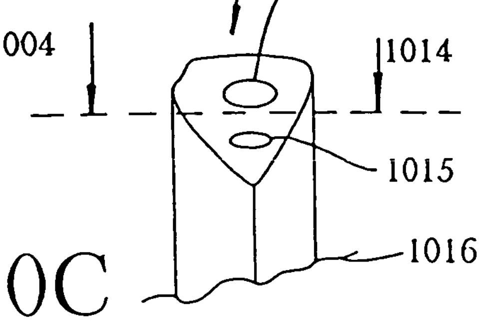


Fig. 10C

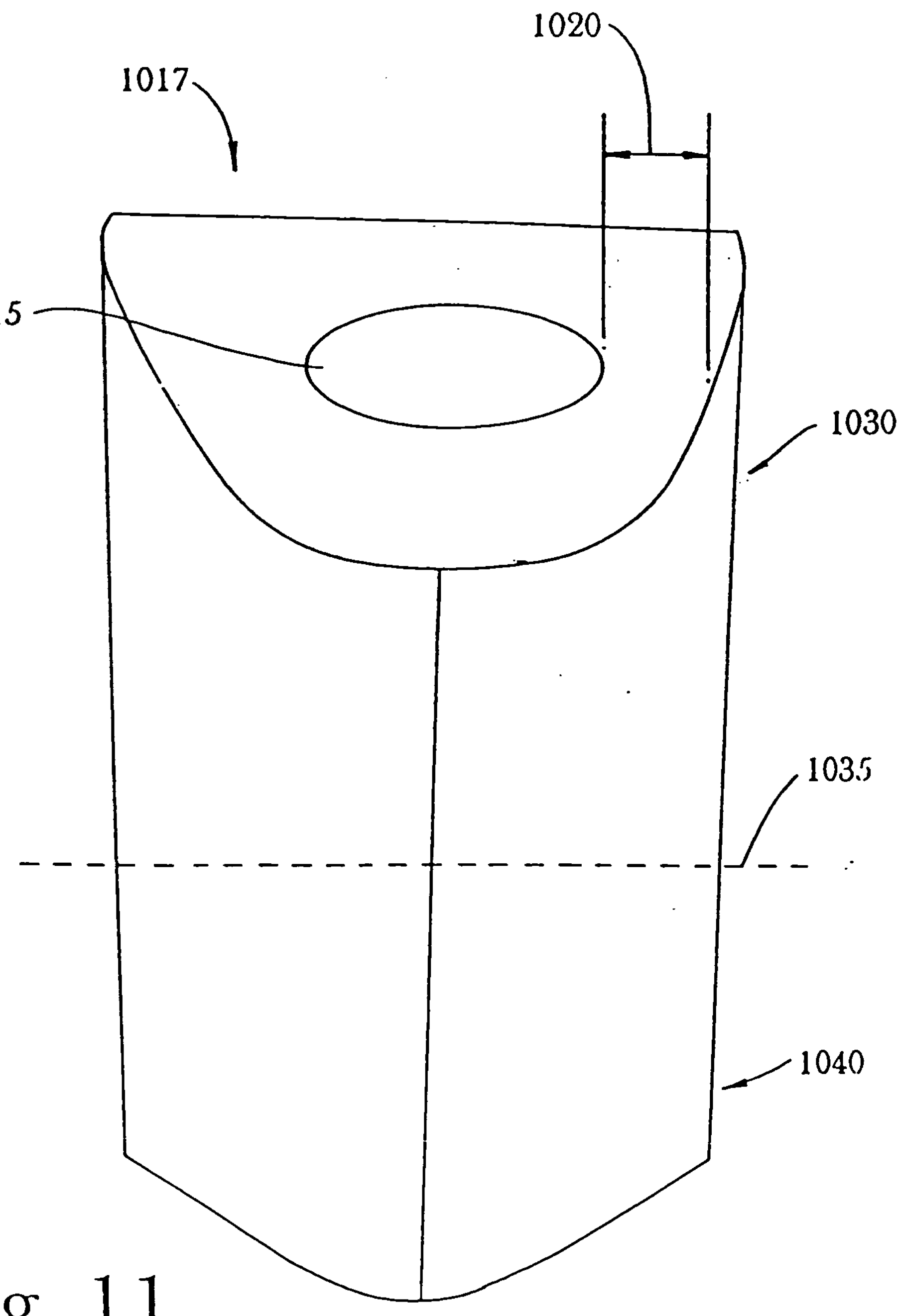


Fig. 11

17/22

Fig. 12A

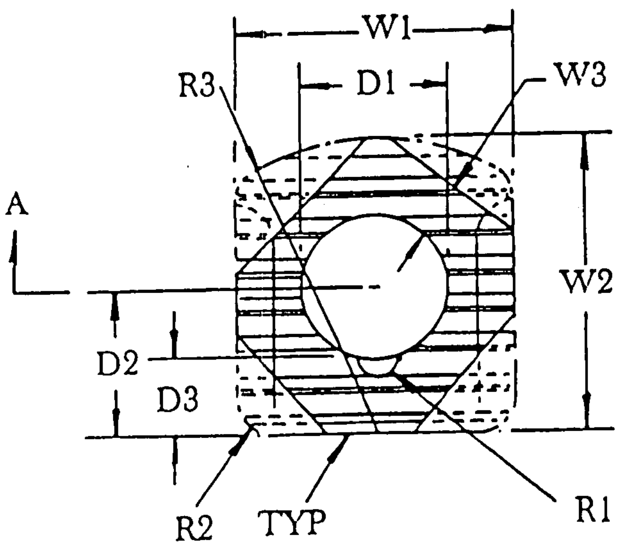


Fig. 12B

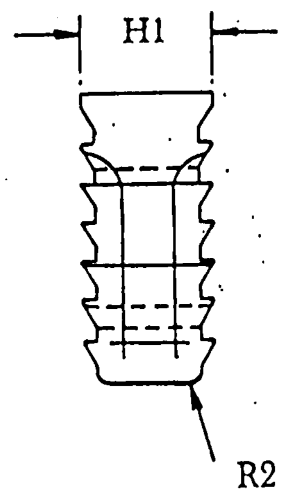
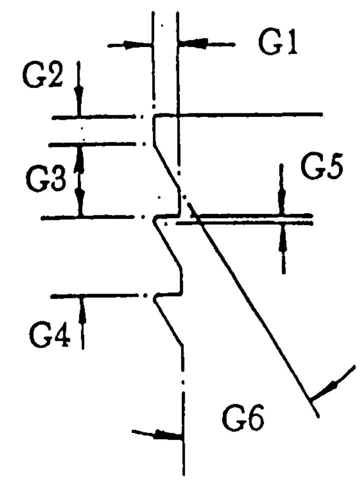


Fig. 12C



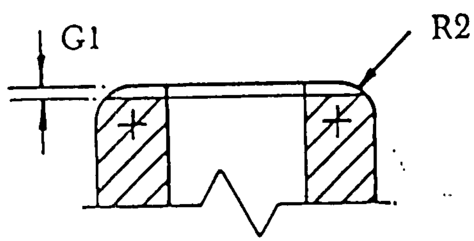


Fig. 12D

Fig. 13A

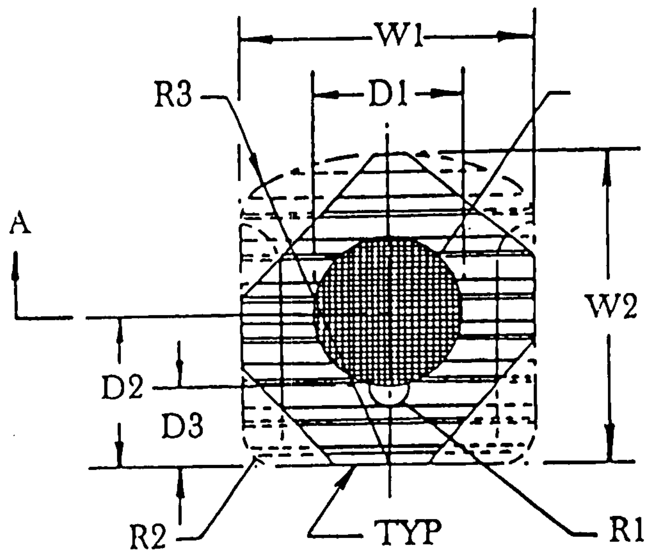


Fig. 13B

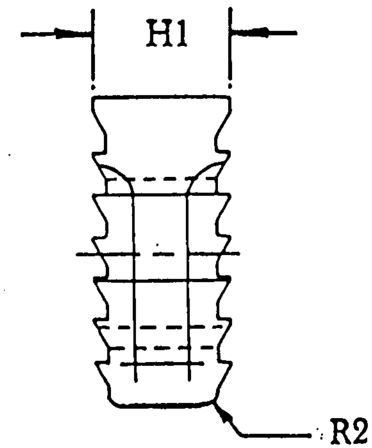
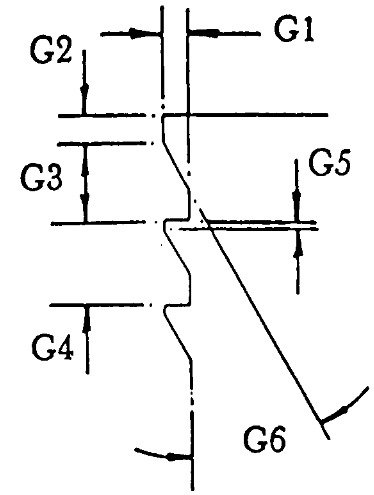


Fig. 13C



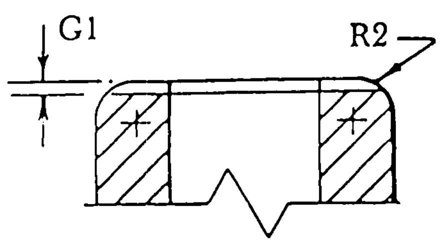


Fig. 13D

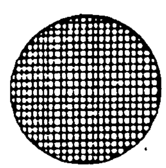


Fig. 13E

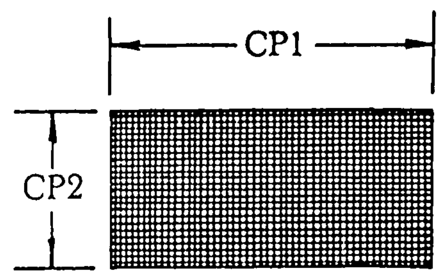


Fig. 13F

Fig. 14A

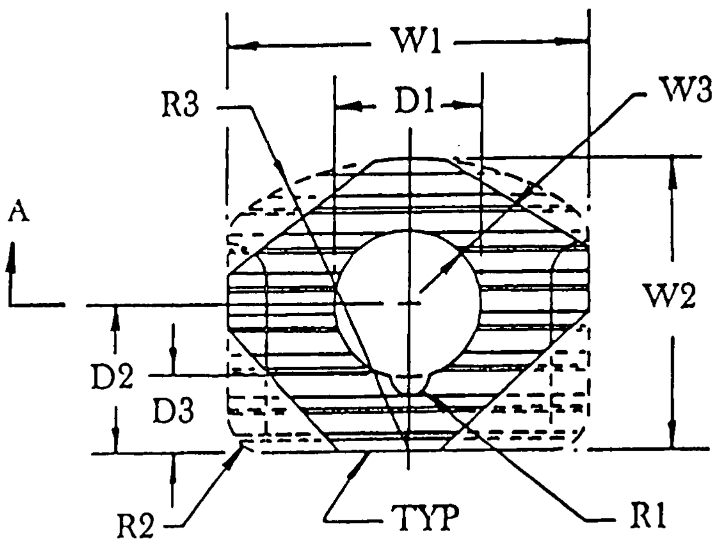


Fig. 14B

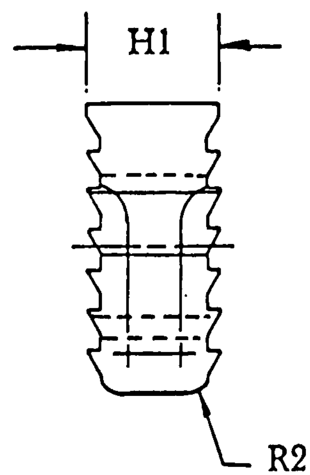
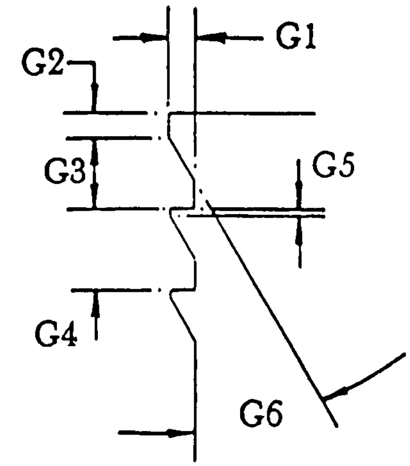


Fig. 14C



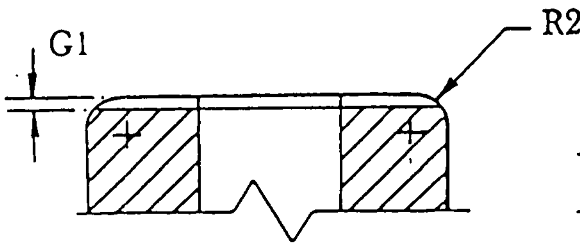


Fig. 14D

Fig. 15A

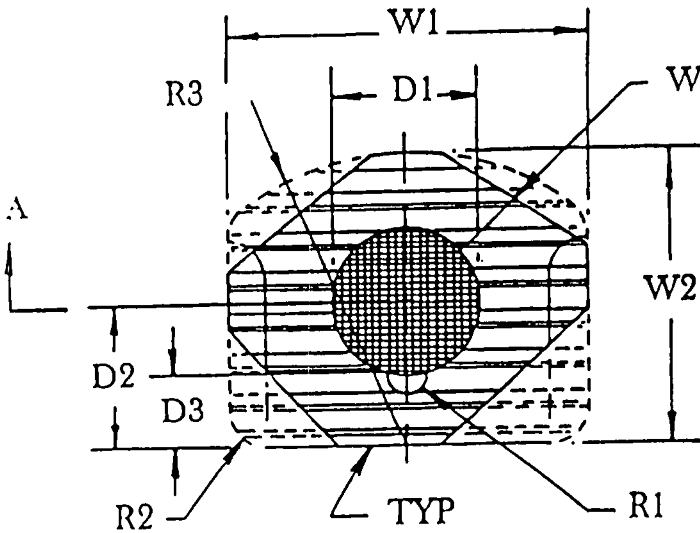


Fig. 15B

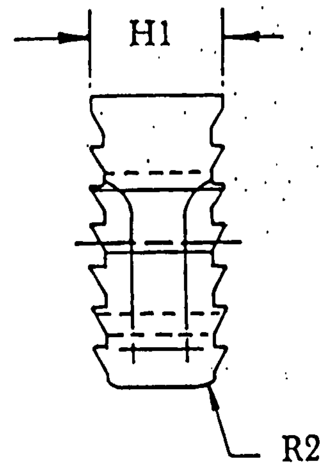
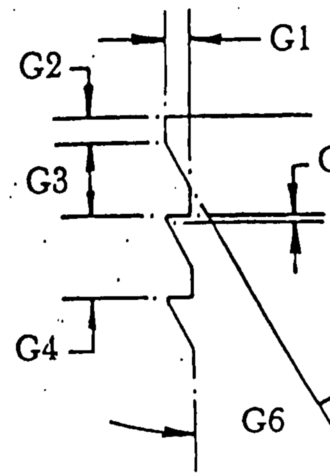


Fig. 15C



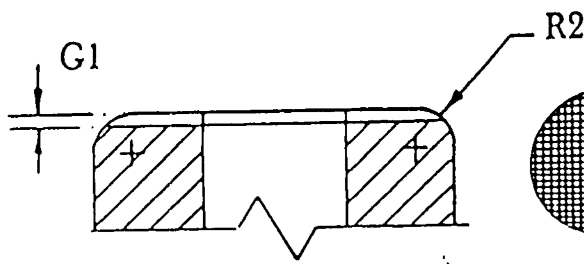


Fig. 15D

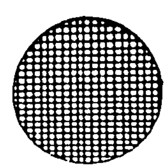


Fig. 15E

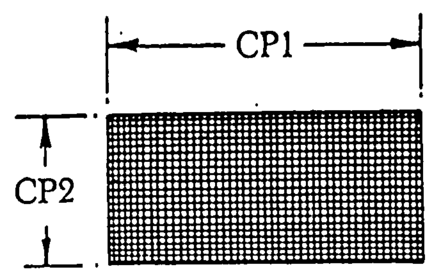


Fig. 15F

Fig. 16A

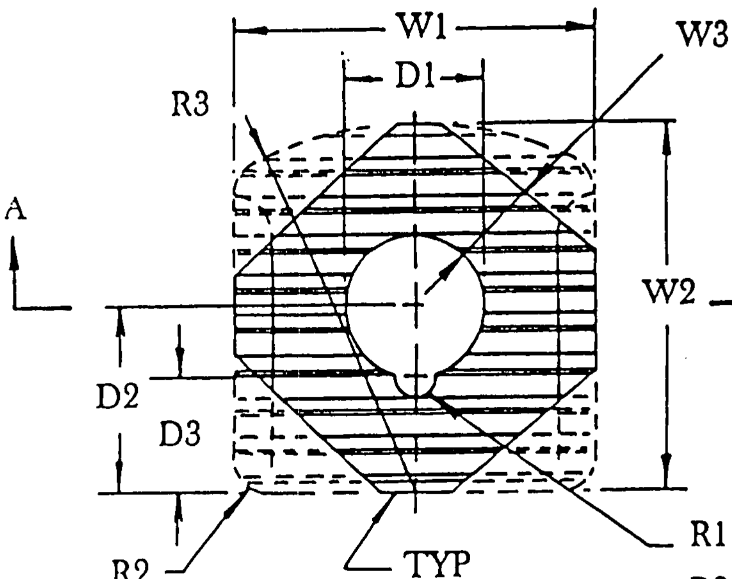


Fig. 16B

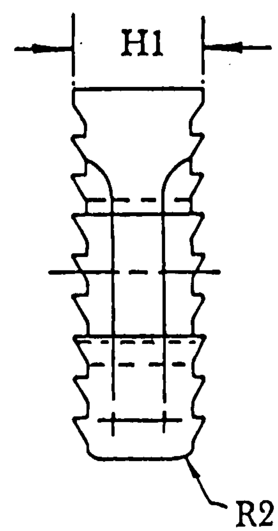
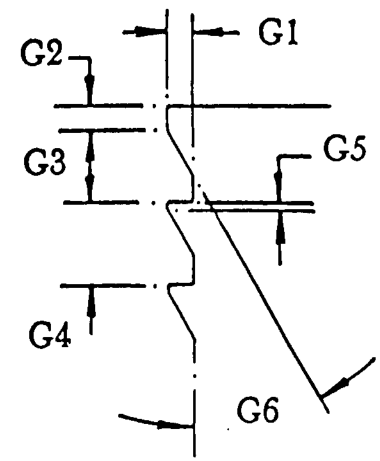


Fig. 16C



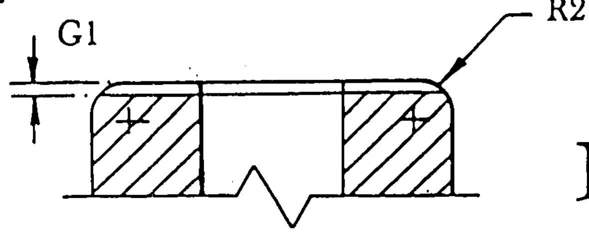


Fig. 16D

Fig. 17A

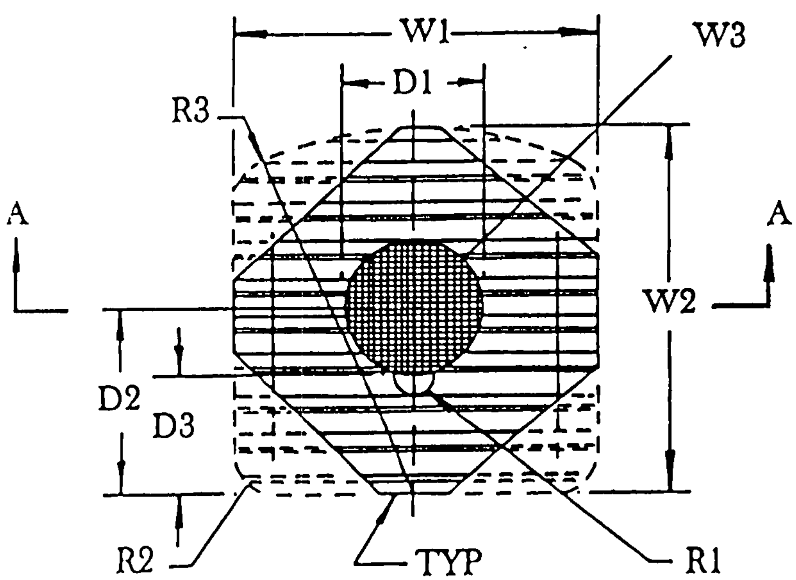


Fig. 17B

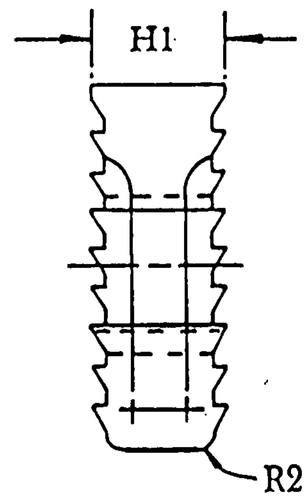
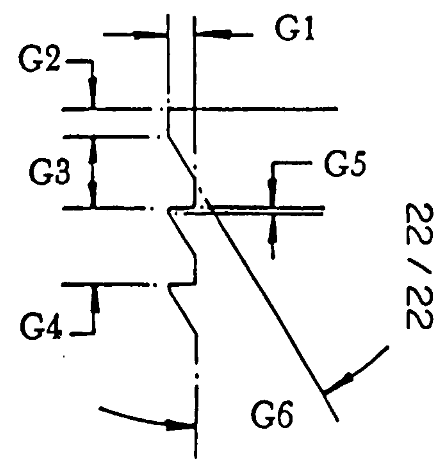


Fig. 17C



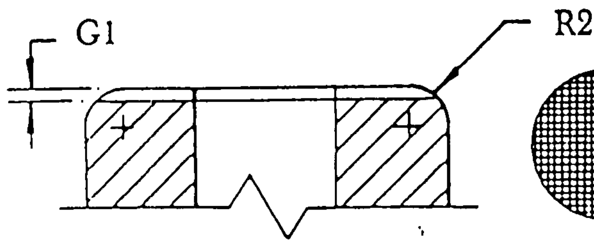


Fig. 17D

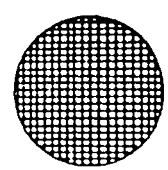


Fig. 17E

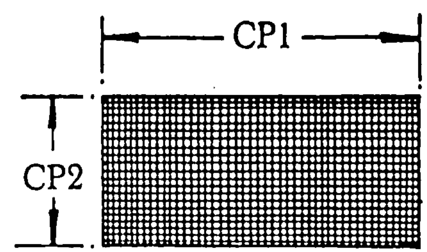


Fig. 17F

UNITED STATES PATENT AND TRADEMARK OFFICE

COMMISSIONER FOR PATENTS
UNITED STATES PATENT AND TRADEMARK OFFICE
WASHINGTON, D.C. 20231
www.uspto.gov

APPLICATION NUMBER	FILING/RECEIPT DATE	FIRST NAMED APPLICANT	ATTORNEY DOCKET NUMBER
09/905,683	07/16/2001	Jamie M. Grooms	TB-104IACA

CONFIRMATION NO. 4376

FORMALITIES LETTER

OC000000007175896

Timothy H. Van Dyke
Bencen & Van Dyke, P.A.
1630 Hillcrest Street
Orlando, FL 32803

Date Mailed: 12/10/2001

NOTICE TO FILE MISSING PARTS OF NONPROVISIONAL APPLICATION

FILED UNDER 37 CFR 1.53(b)

Filing Date Granted

An application number and filing date have been accorded to this application. The item(s) indicated below, however, are missing. Applicant is given **TWO MONTHS** from the date of this Notice within which to file all required items and pay any fees required below to avoid abandonment. Extensions of time may be obtained by filing a petition accompanied by the extension fee under the provisions of 37 CFR 1.136(a).

- The statutory basic filing fee is missing.
  Applicant must submit $ **710** *to complete the basic filing fee for a non-small entity. If appropriate, applicant may make a written assertion of entitlement to small entity status and pay the small entity filing fee (37 CFR 1.27).*
- Total additional claim fee(s) for this application is $1404.
  - **$684** for **38** total claims over 20.
  - **$720** for **9** independent claims over 3 .
- The oath or declaration is unsigned.
- To avoid abandonment, a late filing fee or oath or declaration surcharge as set forth in 37 CFR 1.16(l) of $130 for a non-small entity, must be submitted with the missing items identified in this letter.
- **The balance due by applicant is $ 2244.**

A copy of this notice MUST be returned with the reply.

Customer Service Center
Initial Patent Examination Division (703) 308-1202

PART 3 - OFFICE COPY

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant(s): Grooms *et al.*

Application No.: 09/905,683

Filed: 7/16/2001

Title: Cortical Bone Cervical Smith-Robinson Fusion Implant

Attorney Docket No.: TB-104IACA

Group Art Unit: 3732

RESPONSE TO NOTICE TO FILE MISSING PARTS OF APPLICATION AND PETITION TO MAKE APPLICATION UNDER 37 CFR § 1.47(a)

Assistant Commissioner for Patents
Washington, D.C. 20231
Attention: Box Missing Parts

Sir:

This is in response to a Notice to File Missing Parts of Application under 37 CFR 1.53(b). Enclosed is a copy of said Notice and the following documents and fees to complete the filing requirements of the above-identified application.

(X) Partially executed Declaration and Power of Attorney. Please see the attached Petition under 37 C.F.R. 1.47(a) for explanation of partial execution. The above-identified application is the same application, which the inventor executed by signing the enclosed declaration.

(X) Statutory basic filing fee of $740.00 (X) Utility ( ) Design

(X) Additional claim fees of $1,440.00 ($684.00 for 38 total claims over 20 and $756.00 for 9 independent claims over 3).

(X) Missing Parts Surcharge of $130.00.

(X) Petiton and fee for a one-month extension of time in the amount of $110.00.

(X) Petition to Make Application Under 37 CFR § 1.47(a) with attachments.

(X) Petiton fee under 37 CFR §1.17(h).

(X) Payment is by credit card. Form PTO-2038 is enclosed.

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope with sufficient postage addressed to: Assistant Commissioner for Patents, Washington, D.C. 20231.

Date of Deposit: March 11, 2002

Typed Name: Timothy H. Van Dyke

Signature:

Respectfully submitted,

By

Timothy H. Van Dyke, Reg. No. 43218

Date: March 11, 2002

Customer No: 29847
Van Dyke & Associates, P.A.
1630 Hillcrest Street
Orlando, FL 32803
Phone: 407-228-0328; Fax: 407-228-0329

UNITED STATES PATENT AND TRADEMARK OFFICE

COMMISSIONER FOR PATENTS
UNITED STATES PATENT AND TRADEMARK OFFICE
WASHINGTON, D.C. 20231
www.uspto.gov

APPLICATION NUMBER	FILING/RECEIPT DATE	FIRST NAMED APPLICANT	ATTORNEY DOCKET NUMBER
09/905,683	07/16/2001	Jamie M. Grooms	TB-104IACA

CONFIRMATION NO. 4376

FORMALITIES LETTER

OC000000007175896

Timothy H. Van Dyke
Bencen & Van Dyke, P.A.
1630 Hillcrest Street
Orlando, FL 32803

Date Mailed: 12/10/2001

NOTICE TO FILE MISSING PARTS OF NONPROVISIONAL APPLICATION

FILED UNDER 37 CFR 1.53(b)

Filing Date Granted

An application number and filing date have been accorded to this application. The item(s) indicated below, however, are missing. Applicant is given **TWO MONTHS** from the date of this Notice within which to file all required items and pay any fees required below to avoid abandonment. Extensions of time may be obtained by filing a petition accompanied by the extension fee under the provisions of 37 CFR 1.136(a).

- The statutory basic filing fee is missing.
  *Applicant must submit $ **710** to complete the basic filing fee for a non-small entity. If appropriate, applicant may make a written assertion of entitlement to small entity status and pay the small entity filing fee (37 CFR 1.27).*
- Total additional claim fee(s) for this application is $1404.
  - **$684** for **38** total claims over 20.
  - **$720** for **9** independent claims over 3 .
- The oath or declaration is unsigned.
- To avoid abandonment, a late filing fee or oath or declaration surcharge as set forth in 37 CFR 1.16(l) of $130 for a non-small entity, must be submitted with the missing items identified in this letter.
- **The balance due by applicant is $ 2244.**

A copy of this notice MUST be returned with the reply.

Customer Service Center
Initial Patent Examination Division (703) 308-1202
PART 2 - COPY TO BE RETURNED WITH RESPONSE

PATENT APPLICATION

DECLARATION AND POWER OF ATTORNEY FOR PATENT APPLICATION	ATTORNEY DOCKET NO. TB-104IACA

As a below named inventor, I hereby declare that:
My residence/post office address and citizenship are as stated below next to my name;
I believe I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter which is claimed and for which a patent is sought on the invention entitled:
Cortical Bone Cervical Smith-Robinson Fusion Implant
the specification of which is attached hereto unless the following box is checked:
( ) was filed on ______________ as US Application Serial No. or PCT International Application Number ______________ and was amended on ______________ (if applicable).
I hereby state that I have reviewed and understood the contents of the above-identified specification, including the claims, as amended by any amendment(s) referred to above. I acknowledge the duty to disclose all information which is material to patentability as defined in 37 CFR 1.56.

Foreign Application(s) and/or Claim of Foreign Priority
I hereby claim foreign priority benefits under Title 35, United States Code Section 119 of any foreign application(s) for patent or inventor(s) certificate listed below and have also identified below any foreign application for patent or inventor(s) certificate having a filing date before that of the application on which priority is claimed:

COUNTRY	APPLICATION NUMBER	DATE FILED	PRIORITY CLAIMED UNDER 35 U.S.C. 119
			YES:____ NO:____
			YES:____ NO:____

Provisional Application
I hereby claim the benefit under Title 35, United States Code Section 119(e) of any United States provisional application(s) listed below:

APPLICATION SERIAL NUMBER	FILING DATE

U.S. Priority Claim
I hereby claim the benefit under Title 35, United States Code, Section 120 of any United States application(s) listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States application in the manner provided by the first paragraph of Title 35, United States Code Section 112, I acknowledge the duty to disclose material information as defined in Title 37, Code of Federal Regulations, Section 1.56(a) which occurred between the filing date of the prior application and the national or PCT international filing date of this application:

APPLICATION SERIAL NUMBER	FILING DATE	STATUS(patented/pending/abandoned)
09/701,933	8/25/1998	Pending
08/920,630	8/27/1997	Pending

POWER OF ATTORNEY:
As a named inventor, I hereby appoint the following attorney(s) and/or agent(s) listed below to prosecute this application and transact all business in the Patent and Trademark Office connected therewith.

Timothy H. Van Dyke, Reg. No. 43218

Send Correspondence to:	**Direct Telephone Calls To:**
Timothy H. Van Dyke **Beneen & Van Dyke, P.A.** **1630 Hillcrest Street** **Orlando, Florida 32803**	**Timothy H. Van Dyke** **407-228-0328**

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Full Name of Inventor: Jamie M. Grooms **Citizenship:** USA

Residence: 1 Innovation Drive, Alachua, Florida 32615

Post Office Address: Same

Jamie M Grooms 9/12/01

Inventor's Signature **Date**

DECLARATION AND POWER OF ATTORNEY FOR PATENT APPLICATION (continued)

ATTORNEY DOCKET NO. TB-104IACA

Full Name of Inventor: Kevin C. Carter (deceased) **Citizenship:** USA

Residence: 1 Innovation Drive, Alachua, Florida 32615

Post Office Address: Same

Inventor's Signature **Date**

Full Name of Inventor: Tom Sander **Citizenship:** USA

Residence: 1 Innovation Drive, Alachua, Florida 32615

Post Office Address: Same

Inventor's Signature **Date** 8-9-01

Full Name of Inventor: David H. Dulebohn **Citizenship:** USA

Residence: 2900 14th Street N.;Suite 3, Naples, Florida 33940

Post Office Address: Same

Inventor's Signature **Date**

Full Name of Inventor: **Citizenship:**

Residence:

Post Office Address:

Inventor's Signature **Date**

Full Name of Inventor: **Citizenship:**

Residence:

Post Office Address:

Inventor's Signature **Date**

Full Name of Inventor: **Citizenship:**

Residence:

Post Office Address:

Inventor's Signature **Date**

DECLARATION AND POWER OF ATTORNEY FOR PATENT APPLICATION (continued) | **ATTORNEY DOCKET NO. TB-104IACA**

Full Name of Inventor: Kevin C. Carter **Citizenship:** USA

Residence: 1 Innovation Drive, Alachua, Florida 32615

Post Office Address: Same

Inventor's Signature ____________________ **Date** ____________________

Full Name of Inventor: Tom Sander **Citizenship:** USA

Residence: 1 Innovation Drive, Alachua, Florida 32615

Post Office Address: Same

Inventor's Signature ____________________ **Date** ____________________

Full Name of Inventor: David H. Dulebohn **Citizenship:** USA

Residence: 2900 14th Street N.;Suite 3, Naples, Florida 33940

Post Office Address: Same

Inventor's Signature David H Dulebohn **Date** 8/28/01

Notary [signature]
Macon, North Carolina

Full Name of Inventor: ____________________ **Citizenship:** ____________________

Residence: ____________________

Post Office Address: ____________________

Inventor's Signature ____________________ **Date** ____________________

Full Name of Inventor: ____________________ **Citizenship:** ____________________

Residence: ____________________

Post Office Address: ____________________

Inventor's Signature ____________________ **Date** ____________________

Full Name of Inventor: ____________________ **Citizenship:** ____________________

Residence: ____________________

Post Office Address: ____________________

Inventor's Signature ____________________ **Date** ____________________

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant(s): Grooms *et al.* Application No.: 09/905,683 Filed: 7/16/2001 Title: Cortical Bone Cervical Smith-Robinson Fusion Implant Attorney Docket No.: TB-104IACA	Group Art Unit: 3732

Assistant Commissioner for Patents
Washington, D.C. 20231

Sir:

PETITION TO MAKE APPLICATION UNDER 37 CFR § 1.47(a)

Enclosed herewith is a Declaration/Power of Attorney signed by all inventors except Mr. Kevin Carter (now deceased). Ms. Diane Carter, has been named administrator of Mr. Kevin Carter's estate. After several verbal and written requests, Ms. Carter has constructively refused to sign the relevant Declaration for this case. Accordingly, the signing inventors hereby Petition that the subject application be made on behalf of themselves and on behalf of the nonsigning legal representative of Mr. Kevin Carter, Ms. Diane Carter.

Statement of Facts

Mr. Kevin Carter co-invented the subject matter claimed in the above-captioned application during the course of his employment with Regeneration Technologies, Inc. (RTI). Under Mr. Carter's employment agreement with RTI, he was under an obligation to assign all rights in the invention to RTI. Incidentally, all inventors in the above-captioned application are under an obligation to assign their rights in the invention to RTI.

The undersigned has conducted telephonic communication on several occasions with Ms. Carter directly and through her attorneys. The undersigned initially spoke to Ms. Carter in November 2001 and explained to her that formal documentation relating to the subject case needed her signature as Administrator of Mr. Kevin Carter's estate. The undersigned also explained that such documentation was required to be filed with the U.S. Patent Trademark Office. Ms. Carter stated that she was represented by counsel, so the undersigned tried to coordinate execution of necessary documents through her counsel at the time. These efforts were unsuccessful due to a lack of responsiveness by Ms. Carter or her counsel.

PETITION UNDER 37 CFR § 1.47(A)

On January 4, the undersigned received a phone call from Ms. Carter, wherein she expressed that she was terminating representation by her then current counsel, and that she was seeking new counsel. She indicated that her new counsel would be contacting the undersigned to coordinate the execution of documents.

As the undersigned did not hear from Ms. Carter after two weeks, the undersigned sent copies of all relevant documents to Ms. Carter on January 17, 2002. This letter kindly requested return of the executed documents by January 22, 2002. This quick turnaround was requested in view of rapidly approaching deadlines and/or extension of time fees that have already been incurred.

On February 11, 2002, the undersigned sent a letter to Ms. Diane Carter (see attached) informing her that unless she immediately return the executed documentation for this and other cases naming Mr. Kevin Carter as an inventor, the undersigned would file a Petition requesting that the Patent Office make the application without her signature on the Declaration. As of the date of this Petition, Ms. Carter has not returned the executed documents. The signing Applicants consider Ms. Carter's lack of action as a constructive refusal to sign the necessary Declaration for the subject application.

Relief Requested

A Notice to File Missing Parts in the above-captioned application was issued on December 10, 2001. This Notice set a deadline of February 10, 2002 for timely submission of an executed inventor Declaration. Since the undersigned had not received the executed Declaration from Ms. Diane Carter, the Applicants could not comply with the requirements set forth in the December 10, 2001 Notice. As a result, an extension of time fee was incurred by the Applicants.

Applicants request that the above-captioned application be made on behalf of the signing inventors themselves and on behalf of the sole nonsigning inventor. A Declaration is submitted herewith containing signatures by all of the inventors except Ms. Carter. Grant of this Petition is requested to avoid unnecessary extension of the fees and/or abandonment of the subject application.

Pursuant to the requirements of 37 CFR 1.47(a), Ms. Diane Carter's last known address, and the address of her attorney, is as follows:

Ms. Diane Carter
8502 NW 35th Road
Gainesville, FL 32606

Mr. Larry Ciesla
P.O. Box 1161
Gainesville, FL 32602

Furthermore the necessary fee under 1.17(h) is provided herewith (see attached Form PTO-2038). Should the Patent Office have any questions or require further information with respect to this matter, Applicants request that the undersigned be contacted immediately.

PETITION UNDER 37 CFR § 1.47(A)

Respectfully submitted,

3-11-2002
Date

Timothy H. Van Dyke, Reg. No. 43218

Customer No: 29847

Van Dyke & Associates, P.A.
1630 Hillcrest Street
Orlando, FL 32803
Phone: 407-228-0328; Fax: 407-228-0329

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope with sufficient postage addressed to: Assistant Commissioner for Patents, Washington, D.C. 20231.

Date of Deposit: 3-11-2002

Typed Name: Timothy H. Van Dyke

Signature:

1630 Hillcrest Street
Orlando, Florida 32803
USA

Van Dyke & Associates, PA

INTELLECTUAL PROPERTY LAW

Phone: (407) 228-0328
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info@patentinternational.com
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TO	:	Ms. Diane Carter – c/o Mr. Larry Ciesla
FAX No.	:	352-375-6249
No of PAGES	:	2 (including cover sheet)
FROM	:	Van Dyke & Associates, P.A.
DATE	:	February 11, 2002
RE:	:	The attached letter

MAIL CONFIRMATION TO FOLLOW

Please see the attached letter. Thank you.

If you do not receive all pages or if any portion of this transmission is not legible, call the sender at (407) 228-0328.

1630 Hillcrest Street
Orlando, Florida 32803
USA

MAR 2 1 2002

Van Dyke & Associates, P.A.

INTELLECTUAL PROPERTY LAW

Phone: (407) 228-0328
Fax: (407) 228-0329
info@patentinternational.com
www.patentinternational.com

February 11, 2002

Ms. Diane Carter
c/o Mr. Larry Ciesla
P.O. Box 1161
Gainesville, FL 32602

COPY OF PAPERS ORIGINALLY FILED

VIA FACSIMILE & MAIL CONFIRMATION

Re: Formal Filing Documents for our Docket Nos: TB-104IACA; RTI-118IB; RTI-118IC, RTI-112RIA & RTI-D1

Dear Ms. Carter:

You are in possession of several patent related documents (declaration/power of attorney and assignments forms) for which your signature is needed as the administrator of Mr. Kevin Carter's estate. As far back as November 2001, I have been communicating with you through your attorneys to explain the purpose of these documents. You have also been told that deadlines exist by which these forms must be submitted to the U.S. Patent and Trademark Office. To date, none of the executed forms have been returned to our office.

My client, Regeneration Technologies, Inc., has incurred attorney's fees and time extension fees to keep some of the underlying patent applications pending. Unless the subject forms are filed in the Patent Office, more fees will be incurred, or worse, the applications may go abandoned. As each day passes, the urgency to file the forms increases. Therefore, unless we are faxed (followed by mail) the documents that we sent to you on January 17, 2002 and January 22, 2002 regarding our Docket Nos. TB-104IACA; RTI-118IB; RTI-118IC, RTI-112RIA & RTI-D1 by **Wednesday, February 13, 2002**, we will proceed to file the necessary documents without your signature. Concurrently, we will file a Petition under 37 CFR 1.47 requesting that the Patent Office accept these documents without your signature given your unwillingness to execute them.

In view of Mr. Kevin Carter's clear obligation to assign his rights to any invention he invented in the scope of his employment with RTI, I was hoping that you would recognize this obligation, and be cooperative in executing the necessary forms. I still hope that we can cooperate, as ultimately it serves both your and RTI's interests.

Sincerely,

Timothy H. Van Dyke
Patent Counsel for Regeneration Technologies, Inc.
TVD/mkk

PRIRTER/FAX/COPIER/SCANNER [redacted]

[redacted]SEND CONFIRMATION REPORT FOR
VAN DY[redacted]ASSOCIATES, P.A.
407 22[redacted]29
FEB-11-02 3:02PM

JOB	START TIME	USAGE	PHONE NUMBER/ADDRESS	TYPE	PAGES	MODE	STATUS
109	2/11 3:00PM	1'08"	3523756249	SEND.............	2/ 2	EC 96	COMPLETED..

TOTAL 1'08" PAGES SENT: 2 PAGES PRINTED: 0

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TO	:	Ms. Diane Carter – c/o Mr. Larry Ciesla
FAX No.	:	352-375-6249
No of PAGES	:	2 (including cover sheet)
FROM	:	Van Dyke & Associates, P.A.
DATE	:	February 11, 2002
RE:	:	The attached letter

MAIL CONFIRMATION TO FOLLOW

Please see the attached letter. Thank you.

If you do not receive all pages or if any portion of this transmission is not legible, call the sender at (407) 228-0328.

PETITION FOR EXTENSION OF TIME UNDER 37 CFR 1.136(a)

Docket Number (Optional)
TB-104IACA

In re Application of: Grooms *et al.*	
Application Number: 09/905,683	Filed: 7/16/2001
For Cortical Bone Cervical Smith-Robinson Fusion Implant	
Group Art Unit: 3732	Examiner: Unknown

This is a request under the provisions of 37 CFR 1.136(a) to extend the period for filing a reply in the above identified application.

The requested extension and appropriate non-small-entity fee are as follows (check time period desired):

- [X] One month (37 CFR 1.17(a)(1)) $ 110.00
- [ ] Two months (37 CFR 1.17(a)(2)) $ 400.00
- [ ] Three months (37 CFR 1.17(a)(3)) $ 920.00
- [ ] Four months (37 CFR 1.17(a)(4)) $ 1,440.00
- [ ] Five months (37 CFR 1.17(a)(5)) $ 1,960.00

COPY OF PAPERS ORIGINALLY FILED

- [ ] Applicant claims small entity status. See 37 CFR 1.27. Therefore the fee amount shown above is reduced by one-half, and the resulting fee is: $_____.
- [ ] A check in the amount of the fee is enclosed.
- [X] Payment by credit card. Form PTO-2038 is attached.
- [ ] The Commissioner has already been authorized to charge fees in this application to a Deposit Account.
- [ ] The Commissioner is hereby authorized to charge any fees which may be required, or credit any overpayment, to Deposit Account Number ________________. I have enclosed a duplicate copy of this sheet.

I am the
- [ ] applicant/inventor
- [ ] assignee of record of the entire interest. See 37 CFR 3.71. Statement under 37 CFR 3.73(b) is enclosed. (Form PTO/SB/96).
- [X] attorney or agent of record.
- [ ] attorney or agent under 37 CFR 1.34(a).
  Registration number if acting under 37 CFR 1.34(a) ________________.

WARNING: Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038.

3-11-2002
Date

[signature]
Signature

Timothy H. Van Dyke
Typed or printed name

NOTE: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required. Submit multiple forms if more than one signature is required, see below.

[X] Total of ____1____ forms are submitted.

03/22/2002 SFELEKE1 00000050 09905683

05 FC:115 110.00 OP

Docket No.: 197319US

IN THE UNITED STATES PATENT & TRADEMARK OFFICE

IN RE APPLICATION OF	:
Jamie M. Grooms et al.	: GROUP ART UNIT: 3732 (Anticipated)
SERIAL NO: 09/905,683	: EXAMINER: M. Priddy (Anticipated)
FILED: 16 July 2001	:

FOR: CORTICAL BONE CERVICAL SMITH-ROBINSON FUSION IMPLANT

37 CFR 1.607(a)(4) AMENDMENT

ASSISTANT COMMISSIONER FOR PATENTS
WASHINGTON, D.C. 20231

SIR:

Please cancel claims 1-58.

Please add claims 59-110 as follows:

59. A composite bone graft, comprising:

a first cortical bone portion comprising one or more cortical bone planks, and having a first face comprising protrusions;

a second cortical bone portion comprising one or more cortical bone planks, and having a second face comprising depressions complimentary to said protrusions provided on said first face, said second cortical bone portion is provided on said first cortical bone portion such that said first face and said second face interlock to form a graft unit; and

a cortical bone locking pin located approximately parallel or perpendicular to the

interface of said first cortical bone portion and said second cortical bone portion, said cortical bone locking pin partially traverses said graft unit, wherein said composite bone graft does not comprise an adhesive.

60. A composite bone graft, comprising:

a first substantially planer cortical bone portion;

a second substantially planer cortical bone portion provided on said first substantially planer cortical bone portion to form a graft unit;

one or more biocompatible mechanical connectors for holding together said graft unit, said one or more biocompatible mechanical connectors are provided perpendicular to or parallel to an interface of said first substantially planer cortical bone portion and said second substantially planer cortical bone portion; and

a through-hole entirely traversing said composite bone graft, said through-hole is disposed substantially perpendicular to interfaces of adjacent bone portion, wherein said composite bone graft does not comprise an adhesive.

61. A composite bone graft, consisting essentially of:

a first substantially planer cortical bone portion;

a second substantially planer cortical bone portion provided on said first substantially planer cortical bone portion to form a graft unit;

one or more biocompatible mechanical connectors for holding together said graft unit, said one or more biocompatible mechanical connectors are provided perpendicular to or parallel to an interface of said first substantially planer cortical bone portion and said second substantially

planer cortical bone portion; and

a through-hole entirely traversing said composite bone graft, said through-hole is disposed substantially perpendicular to interfaces of adjacent bone portions.

62. A composite bone graft, comprising:

two or more distinct, adjacent, cortical bone portions, said distinct, adjacent, cortical bone portions each comprising a face complimentary to a face on an adjacent cortical bone portion, each face comprising projections or depressions, such that adjacent faces are complimentary, and a single projection interlocks with a single depression, to provide an interlocking fit between said adjacent bone portions; and

a through-hole entirely traversing said composite bone graft, said through-hole is disposed substantially perpendicular to interfaces of adjacent bone portions, wherein said composite bone graft does not comprise an adhesive.

63. A composite bone graft, consisting essentially of:

two or more distinct, adjacent, cortical bone portions, said distinct, adjacent, cortical bone portions each comprising a face complimentary to a face on an adjacent cortical bone portion, each face comprising projections or depressions, such that adjacent faces are complimentary, and a single projection interlocks with a single depression, to provide an interlocking fit between said adjacent bone portions;

one or more locking pins comprising cortical bone, partially or entirely traversing a dimension of said composite bone graft, said one or more locking pins provided perpendicular to or parallel to an interface between adjacent bone portions, and

a through-hole entirely traversing said composite bone graft, said through-hole is disposed substantially perpendicular to interfaces of adjacent bone portions.

64. A composite bone graft, comprising:

two or more distinct, adjacent, cortical bone portions, said distinct, adjacent, cortical bone portions each comprising a face complimentary to a face on an adjacent cortical bone portion, each face comprising projections or depressions, such that adjacent faces are complimentary, and a single projection interlocks with a single depression, to provide an interlocking fit between said adjacent bone portions;

one or more locking pins comprising cortical bone, partially or entirely traversing a dimension of said composite bone graft, said one or more locking pins provided perpendicular to or parallel to an interface between adjacent bone portions; and

a through-hole entirely traversing said composite bone graft, said through-hole is disposed substantially perpendicular to interfaces of said adjacent bone portions, wherein said composite bone graft does not comprise an adhesive.

65. A composite bone graft, comprising:

two or more distinct, adjacent, bone portions layered to form a graft unit; one or more biocompatible mechanical connectors provided perpendicular to an interface between adjacent bone portions; and a first chamfered edge and a second chamfered edge, said first chamfered edge provided along a length of said composite bone graft at its top edge, and said second chamfered edge provided along a length of said composite bone graft at its bottom edge, such that the chamfered edges are diametrically opposed; and

a through-hole entirely traversing said composite bone graft, said through-hole is disposed substantially perpendicular to interfaces of portions adjacent bone portion, wherein said composite bone graft does not comprise an adhesive.

66. A composite bone graft, comprising:

a first cortical bone portion;

a second cortical bone portion provided on said first cortical bone portion to form a graft unit;

one or more biocompatible mechanical connectors for holding together said graft unit, said one or more biocompatible mechanical connectors are provided perpendicular to or parallel to an interface of said first cortical bone portion and said second cortical bone portion; and

a through-hole entirely traversing said composite bone graft, said through-hole is disposed substantially perpendicular to interfaces of adjacent bone portions, wherein said composite bone graft does not comprise an adhesive.

67. The composite bone graft of claim 66, said first cortical bone portion comprises one or more cortical bone planks, and said second cortical bone portion comprises one or more cortical bone planks.

68. The composite bone graft of claim 67, said first cortical bone portion comprises a first face comprising a [single] protrusion and said second cortical bone portion comprises a second face comprising a [single] depression complimentary to said first face, such that said first face and said second face interlock wherein said composite bone graft does not comprise an adhesive.

69. The composite bone graft of claim 68, said one or more biocompatible mechanical connectors comprise a single cortical bone pin.

70. The composite bone graft of claim 69, said cortical bone pin comprises a locking pin, said locking pin partially traverses said graft unit and is located approximately parallel or perpendicular to the interface of said first cortical bone portion and said second cortical bone portion.

71. The composite bone graft of any one of claims 60, 62, 64, 65, or 66, said composite bone graft further comprising a first top surface and a second bottom surface, said first top surface and said second bottom surface comprising a plurality of protrusions defining a saw-tooth pattern.

72. A composite cervical wedge, comprising:

a first substantially planer cortical bone portion;

a second substantially planer cortical bone portion provided on said first substantially planer cortical bone portion to form a graft unit said graft unit having a top textured surface and a bottom textured surface;

one or more biocompatible mechanical connectors for holding together said graft unit, said one or more biocompatible mechanical connectors are provided perpendicular to or parallel to an interface of said first substantially planer cortical bone portion and said second substantially planer cortical bone portion; and

a through-hole entirely traversing said composite bone graft, said through-hole is disposed substantially perpendicular to interfaces of adjacent bone portions, forming said

composite cervical wedge, said composite cervical wedge comprises:

a first width of from about 7 mm-14 mm; a second width of from about 7 mm-14 mm; a composite anterior height of from about 7 mm-14 mm; a composite posterior height of from about 7 mm-14 mm; and a diameter of from about 7 mm-14 mm, wherein said top textured surface and said bottom textured surface are opposing and are disposed parallel to interfaces of said bone portions, said top textured surface and said bottom textured surface comprises a plurality of protrusions defining a saw-tooth pattern, and wherein said composite bone graft does not comprise an adhesive.

73. A composite cervical block, comprising:

a first substantially planer cortical bone portion;

a second substantially planer cortical bone portion provided on said first substantially planer cortical bone portion to form a graft unit said graft unit having a top textured surface and a bottom textured surface;

one or more biocompatible mechanical connectors for holding together said graft unit, said one or more biocompatible mechanical connectors are provided perpendicular to or parallel to an interface of said first substantially planer cortical bone portion and said second substantially planer cortical bone portion; and

a through-hole entirely traversing said composite bone graft, said through-hole is disposed substantially perpendicular to interfaces of adjacent bone portions, forming said composite cervical wedge, said composite cervical wedge comprises:

a first width of from about 7 mm-14 mm; a second width of from about 7 mm-14 mm; a

composite height of from about 7 mm-14 mm; and a diameter of from about 7 mm-14 mm, wherein said top textured surface and said bottom textured surface are opposing and are disposed parallel to interfaces of said bone portions, said top textured surface and said bottom textured surface comprises a plurality of protrusions defining a saw-tooth pattern, and wherein said composite bone graft does not comprise an adhesive.

74. The composite bone graft of any one of claims 60, 62, 64-66, 72, or 73, further comprising osteogenic materials provided in said through-hole, said osteogenic materials comprising demineralized bone.

75. The composite bone graft of claim 74, said osteogenic materials further comprising bone morphogenic protein.

76. The composite bone graft of claim 75, said through-hole has a diameter of from about 2.0 mm to about 8.0 mm.

77. The composite bone graft of any one of claims 59, 60, 62, 64-66, 72, or 73, said bone portions comprising allogenic bone.

78. The composite bone graft of claim 65, said two or more distinct, adjacent, bone portions comprise one or more members selected from the group consisting of cortical bone and cancellous bone.

79. The composite bone graft of claim 78, said cortical bone and said cancellous bone, comprising allogenic bone.

80. The composite bone graft of claim 65, said composite bone graft further comprising a top surface; a bottom surface; a diameter of from about 7 mm-14 mm; a width of from about 7 mm-14 mm; an anterior composite height of from about 7 mm-14 mm; and a posterior composite height of from about 7 mm-14 mm.

81. The composite bone graft of claim 80, said top surface and said bottom surface comprising a plurality of protrusions defining a saw-tooth pattern.

82. The composite bone graft of any one of claims 73 or 81, said plurality of protrusions having a height of about 4 mm.

83. The composite bone graft of any one of claims 60, 61, 66, 72, or 73, said first cortical bone portion comprises one or more cortical bone planks, and said second cortical bone portion comprises one or more cortical bone planks.

84. The composite bone graft of any one of claims 62-64 or 65, each of said cortical bone portions comprises one or more cortical bone planks.

85. The composite bone graft of claim 71, said plurality of protrusions having a height of about 4 mm.

86. A composite bone graft, comprising:

a first cortical bone portion comprising one or more cortical bone planks, and having a first face comprising protrusions;

a second cortical bone portion comprising one or more cortical bone planks, and having a

second face comprising depressions complimentary to said protrusions provided on said first face, said second cortical bone portion is provided on said first cortical bone portion such that said first face and said second face interlock to form a graft unit; and

a cortical bone locking pin located approximately parallel or perpendicular to the interface of said first cortical bone portion and said second cortical bone portion, said cortical bone locking pin partially traverses said graft unit.

87. A composite bone graft, comprising:

a first substantially planer cortical bone portion;

a second substantially planer cortical bone portion provided on said first substantially planer cortical bone portion to form a graft unit;

one or more biocompatible mechanical connectors for holding together said graft unit, said one or more biocompatible mechanical connectors are provided perpendicular to or parallel to an interface of said first substantially planer cortical bone portion and said second substantially planer cortical bone portion; and

a through-hole entirely traversing said composite bone graft, said through-hole is disposed substantially perpendicular to interfaces of adjacent bone portion.

88. A composite bone graft, comprising:

two or more distinct, adjacent, cortical bone portions, said distinct, adjacent, cortical bone portions each comprising a face complimentary to a face on an adjacent cortical bone portion, each face comprising projections or depressions, such that adjacent faces are complimentary, and a single projection interlocks with a single depression, to provide an interlocking fit between said

adjacent bone portions; and

a through-hole entirely traversing said composite bone graft, said through-hole is disposed substantially perpendicular to interfaces of adjacent bone portions.

89. A composite bone graft, comprising:

two or more distinct, adjacent, cortical bone portions, said distinct, adjacent, cortical bone portions each comprising a face complimentary to a face on an adjacent cortical bone portion, each face comprising projections or depressions, such that adjacent faces are complimentary, and a single projection interlocks with a single depression, to provide an interlocking fit between said adjacent bone portions;

one or more locking pins comprising cortical bone, partially or entirely traversing a dimension of said composite bone graft, said one or more locking pins provided perpendicular to or parallel to an interface between adjacent bone portions; and

a through-hole entirely traversing said composite bone graft, said through-hole is disposed substantially perpendicular to interfaces of said adjacent bone portions.

90. A composite bone graft, comprising:

two or more distinct, adjacent, bone portions layered to form a graft unit; one or more biocompatible mechanical connectors provided perpendicular to an interface between adjacent bone portions; and a first chamfered edge and a second chamfered edge, said first chamfered edge provided along a length of said composite bone graft at its top edge, and said second chamfered edge provided along a length of said composite bone graft at its bottom edge, such that the chamfered edges are diametrically opposed; and

a through-hole entirely traversing said composite bone graft, said through-hole is disposed substantially perpendicular to interfaces of portions adjacent bone portion.

91. A composite bone graft, comprising:

a first cortical bone portion;

a second cortical bone portion provided on said first cortical bone portion to form a graft unit;

one or more biocompatible mechanical connectors for holding together said graft unit, said one or more biocompatible mechanical connectors are provided perpendicular to or parallel to an interface of said first cortical bone portion and said second cortical bone portion; and

a through-hole entirely traversing said composite bone graft, said through-hole is disposed substantially perpendicular to interfaces of adjacent bone portions .

92. The composite bone graft of claim 91, said first cortical bone portion comprises one or more cortical bone planks, and said second cortical bone portion comprises one or more cortical bone planks.

93. The composite bone graft of claim 92, said first cortical bone portion comprises a first face comprising a protrusion and said second cortical bone portion comprises a second face comprising a depression complimentary to said first face, such that said first face and said second face interlock wherein said composite bone graft does not comprise an adhesive.

94. The composite bone graft of claim 93, said one or more biocompatible mechanical connectors comprise a single cortical bone pin.

95. The composite bone graft of claim 94, said cortical bone pin comprises a locking pin, said locking pin partially traverses said graft unit and is located approximately parallel or perpendicular to the interface of said first cortical bone portion and said second cortical bone portion.

96. The composite bone graft of any one of claims 87, 88, 89, 90, or 91, said composite bone graft further comprising a first top surface and a second bottom surface, said first top surface and said second bottom surface comprising a plurality of protrusions defining a saw-tooth pattern.

97. A composite cervical wedge, comprising:

a first substantially planer cortical bone portion;

a second substantially planer cortical bone portion provided on said first substantially planer cortical bone portion to form a graft unit, said graft unit having a top textured surface and a bottom textured surface;

one or more biocompatible mechanical connectors for holding together said graft unit, said one or more biocompatible mechanical connectors are provided perpendicular to or parallel to an interface of said first substantially planer cortical bone portion and said second substantially planer cortical bone portion; and

a through-hole entirely traversing said composite bone graft, said through-hole is disposed substantially perpendicular to interfaces of adjacent bone portions, forming said composite cervical wedge, said composite cervical wedge comprises:

a first width of from about 7 mm-14 mm}; a second width of from about 7 mm-14 mm; a

composite anterior height of from about 7 mm-14 mm; a composite posterior height of from about 7 mm-14 mm; and a diameter of from about 7 mm-14 mm, wherein said top textured surface and said bottom textured surface are opposing and are disposed parallel to interfaces of said bone portions, said top textured surface and said bottom textured surface comprises a plurality of protrusions defining a saw-tooth pattern.

98. A composite cervical block, comprising:

a first substantially planer cortical bone portion;

a second substantially planer cortical bone portion provided on said first substantially planer cortical bone portion to form a graft unit, said graft unit having a top textured surface and a bottom textured surface;

one or more biocompatible mechanical connectors for holding together said graft unit , said one or more biocompatible mechanical connectors are provided perpendicular to or parallel to an interface of said first substantially planer cortical bone portion and said second substantially planer cortical bone portion; and

a through-hole entirely traversing said composite bone graft, said through-hole is disposed substantially perpendicular to interfaces of adjacent bone portions, forming said composite cervical wedge, said composite cervical wedge comprises:

a first width of from about 7 mm-14 mm; a second width of from about 7 mm-14 mm; a composite height of from about 7 mm-14 mm; and a diameter of from about 7 mm-14 mm, wherein said top textured surface and said bottom textured surface are opposing and are disposed parallel to interfaces of said bone portions, said top textured surface and said bottom textured

surface comprises a plurality of protrusions defining a saw-tooth pattern.

99. The composite bone graft of any one of claims 87-91, 97, or 98, further comprising osteoinductive substances provided in said through-hole, said osteoinductive substances are selected from the group consisting of demineralized bone and bone marrow cancellous bone.

100. The composite bone graft of claim 99, said osteoinductive substances further comprising one or more members selected from the group consisting of bone morphogenic protein and a growth factor.

101. The composite bone graft of claim 100, said through-hole has a diameter of from about 2.0 mm to about 8.0 mm.

102. The composite bone graft of any one of claims 86-91, 97, or 98, said bone portions comprising allogenic bone.

103. The composite bone graft of claim 90, said two or more distinct, adjacent, bone portions comprise one or more members selected from the group consisting of cortical bone and cancellous bone.

104. The composite bone graft of claim 103, said cortical bone and said cancellous bone, comprising allogenic bone.

105. The composite bone graft of claim 90, said composite bone graft further comprising a top surface; a bottom surface; a diameter of from about 7 mm-14 mm; a width of from about 7 mm-

14 mm; an anterior composite height of from about 7 mm-14 mm; and a posterior composite height of from about 7 mm-14 mm.

106. The composite bone graft of claim 105, said top surface and said bottom surface comprising a plurality of protrusions defining a saw-tooth pattern.

107. The composite bone graft of any one of claims 98 or 106, said plurality of protrusions having a height of about 4 mm.

108. The composite bone graft of any one of claims 61, 87, 91, 97, or 98, said first cortical bone portion comprises one or more cortical bone planks, and said second cortical bone portion comprises one or more cortical bone planks.

109. The composite bone graft of any one of claims 63, 88, 89, or 90, each of said cortical bone portions comprises one or more cortical bone planks.

110. The composite bone graft of claim 96, said plurality of protrusions having a height of about 4 mm.

REMARKS

Claims 1-58 have been canceled.

Claims 59-110 are patterned after claims 1-27 of U.S. patent No. 6,200,347 B1 issued 13 March 2001, and they have been presented to provoke an interference with that patent.

Respectfully submitted,

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JAN 30 2002

PTO-850-(Rev. 09-22-97) (OSMMN version) Count # 1

INTERFERENCE-INITIAL MEMORANDUM

BOARD OF PATENT APPEALS AND INTERFERENCES: An interference is found to exist between the following cases:

This interference involves 2 Parties

EXAMINERS INSTRUCTIONS - This form need not be typewritten. Complete the items below and forward to the Group Clerk with all file including those benefit of which has been accorded. The parties need not be listed in any specific order. Use a separate form of each count.

(See MPEP 2309.02)

BOARD OF PATENT APPEALS AND INTERFERENCES: An interference is found to exist between the following cases:

1. PARTY	APPLICATION NO.	FILING DATE	PATENT NO., IF ANY	ISSUE DATE, IF ANY
Grooms et al.	09/905,683	16 July 2001		

If application has been patented, have maintenance fees been paid? ______Yes _____No _____Maintenance Fees not due yet

The claims of this party which correspond to this count are: 59-110.
The claims of this party which do not correspond to this count are: None

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*Accorded the benefit of:

COUNTRY	APPLICATION NO.	FILING DATE	PATENT NO., IF ANY	ISSUE DATE, IF ANY
U.S.	09/701,933	27 August 1998		
U.S.	08/920,630	27 August 1987		

2. PARTY	APPLICATION NO.	FILING DATE	PATENT NO., IF ANY	ISSUE DATE, IF ANY
Anderson et al.	09/368,263	03 August 1999	6,200,347 B1	13 March 2001

If application has been patented, have maintenance fees been paid? ______Yes _____No __X__ Maintenance Fees not due yet

The claims of this party which correspond to this count are: 1-27. The claims of this party which do not correspond to this count are: None

*Accorded the benefit of:

COUNTRY	APPLICATION NO.	FILING DATE	PATENT NO., IF ANY	ISSUE DATE, IF ANY
None				

3. PARTY	APPLICATION NO.	FILING DATE	PATENT NO., IF ANY	ISSUE DATE, IF ANY

If application has been patented, have maintenance fees been paid? ______Yes ____ No ____ Maintenance Fees not due yet

The claims of this party which correspond to this count are: The claims of this party which do not correspond to this count are:

*Accorded the benefit of:

COUNTRY	APPLICATION NO.	FILING DATE	PATENT NO., IF ANY	ISSUE DATE, IF ANY

Instructions

1. For every patent involved in the interf[illegible], check if the maintenance fees have been paid by usin[illegible]atent Number with PALM screen 2970. If fees are due and they have not been paid, the Interference cannot be declared since it would involved an expired patent (35 U.S.C. §135(a), 37 C.F.R. §1.606)
2. For each party, identify the patentable (or patented) and unpatentable (pending) claims which correspond to the count (37 C.F.R. §1.60(f), (n); §1.609(b)(2)).
3. For each party, identify the patentable (or patented) and unpatentable (pending) claims which do not correspond to the count of (37 C.F.R. §1.609(b)(3)).
4. Forward all files including those the benefit of which is being accorded.
5. Keep a copy of the Interference Initial Memorandum and any attachments for your records.

All Information Requested Below Must Be Attached On (a) Separate Typewritten Sheet(s).

6. On a separate sheet, set forth a single proposed interference count. If any claim or any party is exactly the same word for word as this count, please indicate the party, application or patent number, and the claim number.

DATE	PRIMARY EXAMINER (signature)	TELEPHONE NO.:	ART UNIT
DATE	GROUP DIRECTOR SIGNATURE (if required)		

* The application number and filing date of each application the benefit of which is intended to be accorded must be listed. It is not sufficient to merely list the earliest.

Count 1

6. Anderson et al.'s claims 1-27 in the alternative

or

Grooms et al.'s claims 59-110 in the alternative.

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Docket No. 197319US

IN THE UNITED STATES PATENT & TRADEMARK OFFICE

IN RE APPLICATION OF:

Jamie M. Grooms et al.	: GROUP ART UNIT: 3732 (Anticipated)
SERIAL NO: 09/905,683	: EXAMINER: M. Priddy (Anticipated)
FILED: 16 July 2001	:

FOR: CORTICAL BONE CERVICAL SMITH-ROBINSON FUSION IMPLANT

37 CFR 1.607 REQUEST FOR AN
INTERFERENCE WITH A PATENT

ASSISTANT COMMISSIONER FOR PATENTS
WASHINGTON, D.C. 20231

SIR:

I. 37 CFR 1.607(a)(1)

The patent is U.S. patent No. 6,200,347 B1 issued March 13, 2001 and naming Billy G. Anderson and Lloyd Wolfinbarger, Jr. as inventors. The assignee at issue was LifeNet of Virginia Beach, VA (US).

II. 37 CFR 1.607(a)(2)

Applicants propose the following count, which is in the format approved by the Commissioner in Orikasa v. Oonishi, 10 USPQ2d 1996, 2003 (Comm'r 1990), and Davis v. Uke, 27 USPQ2d 1180, 1188 (Comm'r 1993):

Claims 1-27 in the Anderson et al. patent

OR

Claims 59-110 in the Grooms et al. application.

An extra copy of the proposed count is submitted herewith for the examiner's use in filling out the form PTO-850. In addition, as explained in Section IX of this request, a proposed form PTO-850 is submitted herewith for the examiner's convenience.

III. 37 CFR 1.607(a)(3)

All 27 claims in the Anderson et al. patent correspond to the proposed count. Indeed, the proposed count includes all the claims in that patent.

IV. 37 CFR 1.607(a)(4)

Claims 59-110 presented in the 37 CFR 1.607(a)(4) amendment submitted herewith correspond to the proposed count. Indeed, the proposed count includes all of the claims in that group of claims.

V. 37 CFR 1.607(a)(5)

The terms of the application claims identified as corresponding to the proposed count and not previously in the application can be applied to the disclosure of the application as shown by the inserts in bold below as follows:

59. A composite bone graft **{page 18 lines 18-20}**, comprising:

a first cortical bone portion comprising one or more cortical bone planks **{Fig. 7; items 711A and 711B}**, and having a first face comprising protrusions **{Fig. 7 pins protrude from item 711A; page 18 line 27-page 19 line 6}**;

a second cortical bone portion comprising one or more cortical bone planks **{Fig. 7, item 711B}**, and having a second face comprising depressions **{Fig. 7 holes for pins in item 711A in item 711B}** complimentary to said protrusions provided on said first face, said second cortical bone portion is provided on said first cortical bone portion such that said first face and said second face interlock to form a graft unit **{Fig. 7 items 711A and 711B}**; and

a cortical bone locking pin located approximately parallel or perpendicular to the interface of said first cortical bone portion and said second cortical bone portion **{Fig. 7 items 711A and 711B; page 18 line 27-page 19 line 6}**, said cortical bone locking pin partially traverses said graft unit, wherein said composite bone graft does not comprise an adhesive.

60. A composite bone graft **{page 18 lines 18-20}**, comprising:

a first substantially planer cortical bone portion **{Fig. 7 item 711A}**;

a second substantially planer cortical bone portion provided on said first substantially planer cortical bone portion to form a graft unit **{Fig. 7, item 711B}**;

one or more biocompatible mechanical connectors for holding together said graft unit **{page 18 line 27-page 19 line 6}**, said one or more biocompatible mechanical connectors are provided perpendicular to or parallel to an interface of said first substantially planer cortical bone portion and said second substantially planer cortical bone portion; and

a through-hole entirely traversing said composite bone graft **{Figs. 1 and 7 item 104; Fig. 7 items 711A and 711B}**, said through-hole is disposed substantially perpendicular to interfaces of adjacent bone portion, wherein said composite bone graft does not comprise an adhesive.

61. A composite bone graft **{page 18 lines 18-20}**, consisting essentially of:

a first substantially planer cortical bone portion **{Fig. 7 item 711A}**;

a second substantially planer cortical bone portion provided on said first substantially planer cortical bone portion to form a graft unit **{Fig. 7 item 711B}**;

one or more biocompatible mechanical connectors for holding together said graft unit **{page 18 line 27-page 19 line 6}**, said one or more biocompatible mechanical connectors are provided perpendicular to or parallel to an interface of said first substantially planer cortical bone portion and said second substantially planer cortical bone portion; and

a through-hole entirely traversing said composite bone graft **{Figs. 1 and 7 item 104; Fig. 7 items 711A and 711B}**, said through-hole is disposed substantially perpendicular to interfaces of adjacent bone portions.

62. A composite bone graft **{page 18 lines 18-20}**, comprising:

two or more distinct, adjacent, cortical bone portions **{Fig. 7 items 711A and 711B}**, said distinct, adjacent, cortical bone portions each comprising a face complimentary to a face on an adjacent cortical bone portion, each face comprising projections or depressions, such that adjacent faces are complimentary, and a single projection interlocks with a single depression, to provide an interlocking fit between said adjacent bone portions **{Fig. 7 pins project from item 711A into depressions (i.e., holes) in item 711B}**; and

a through-hole entirely traversing said composite bone graft **{Figs. 1 and 7 item 104; Fig. 7 items 711A and 711B}**, said through-hole is disposed substantially perpendicular to interfaces of adjacent bone portions **{Fig. 7 items 711A and 711B}**, wherein said composite bone graft does not comprise an adhesive.

63. A composite bone graft **{page 18 lines 18-20}**, consisting essentially of:

two or more distinct, adjacent, cortical bone portions **{Fig. 7 items 711A and 711B}**, said distinct, adjacent, cortical bone portions each comprising a face complimentary to a face on an adjacent cortical bone portion, each face comprising projections or depressions, such that adjacent faces are complimentary, and a single projection interlocks with a single depression, to provide an interlocking fit between said adjacent bone portions **{Fig. 7 pins project from item 711A into depressions in item 711B}**;

one or more locking pins comprising cortical bone, partially or entirely traversing a dimension of said composite bone graft **{page 18 line 27-page 19 line 6}**, said one or more locking pins provided perpendicular to or parallel to an interface between adjacent bone portions **{Fig. 7 items 711A and 711B}**, and

a through-hole entirely traversing said composite bone graft **{Figs. 1 and 7 item 104; Fig. 7 items 711A and 711B}**, said through-hole is disposed substantially perpendicular to interfaces of adjacent bone portions **{Fig. 7 items 711A and 711B}**.

64. A composite bone graft **{page 18 lines 18-20}**, comprising:

two or more distinct, adjacent, cortical bone portions **{Fig. 7 items 711A and 711B)**, said distinct, adjacent, cortical bone portions each comprising a face complimentary to a face on an

adjacent cortical bone portion, each face comprising projections or depressions, such that adjacent faces are complimentary, and a single projection interlocks with a single depression, to provide an interlocking fit between said adjacent bone portions **{Fig. 7 pins project from item 711A into depressions in item 711B}**;

one or more locking pins comprising cortical bone **{page 18 line 27-page 19 line 6}**, partially or entirely traversing a dimension of said composite bone graft, said one or more locking pins provided perpendicular to or parallel to an interface between adjacent bone portions **{Fig. 7 items 711A and 711B}**; and

a through-hole entirely traversing said composite bone graft **{Figs. 1 and 7 item 104}**, said through-hole is disposed substantially perpendicular to interfaces of said adjacent bone portions **{Fig. 7 items 711A and 711B}**, wherein said composite bone graft does not comprise an adhesive.

65. A composite bone graft **{page 18 lines 18-20}**, comprising:

two or more distinct, adjacent, bone portions layered to form a graft unit **{Fig. 7 items 711A and 711B}**; one or more biocompatible mechanical connectors provided perpendicular to an interface between adjacent bone portions **{Fig. 7 items 711A and 711B; page 18 line 27-page 19 line 6}**; and a first chamfered edge **{Figs. 1D-E item 115}** and a second chamfered edge **{Figs. 1D-E item 115}**, said first chamfered edge provided along a length of said composite bone graft at its top edge **{Figs. 1C-D}**, and said second chamfered edge provided along a length of said composite bone graft at its bottom edge **{Figs. 1C-D}**, such that the chamfered edges are diametrically opposed **{Fig. 1C item 115}**; and

a through-hole entirely traversing said composite bone graft **{Figs. 1 and 7 item 104}**, said through-hole is disposed substantially perpendicular to interfaces of portions adjacent bone portion **{Fig. 7 items 711A and 711B}**, wherein said composite bone graft does not comprise an adhesive.

66. A composite bone graft **{page 18 lines 18-20}**, comprising:

a first cortical bone portion **{Fig. 7 item 711A}**;

a second cortical bone portion provided on said first cortical bone portion to form a graft unit **{Fig. 7 item 711B}**;

one or more biocompatible mechanical connectors for holding together said graft unit **{page 18 line 27-page 19 line 6}**, said one or more biocompatible mechanical connectors are provided perpendicular to or parallel to an interface of said first cortical bone portion and said second cortical bone portion **{Fig. 7 items 711A and 711B}**; and

a through-hole entirely traversing said composite bone graft **{Figs. 1 and 7 item 104}**, said through-hole is disposed substantially perpendicular to interfaces of adjacent bone portions **{Fig. 7 items 711A and711B}**, wherein said composite bone graft does not comprise an adhesive.

67. The composite bone graft of claim 66, said first cortical bone portion comprises one or more cortical bone planks **{Fig. 7 item 711A}**, and said second cortical bone portion comprises one or more cortical bone planks **{Fig. 7 item 711B}**.

68. The composite bone graft of claim 67, said first cortical bone portion comprises a first face comprising a protrusion and said second cortical bone portion comprises a second face comprising a depression complimentary to said first face, such that said first face and said second face interlock **{page 18 line 27-page 19 line 6}** wherein said composite bone graft does not comprise an adhesive.

69. The composite bone graft of claim 68, said one or more biocompatible mechanical connectors comprise a single cortical bone pin **{page 18 line 27-page 19 line 6}**.

70. The composite bone graft of claim 69, said cortical bone pin comprises a locking pin **{page 18 line 27-page 19 line 6}**, said locking pin partially traverses said graft unit and is located approximately parallel or perpendicular to the interface of said first cortical bone portion and said second cortical bone portion **{Fig. 7 items 711A and 711B}**.

71. The composite bone graft of any one of claims 60, 62, 64, 65, or 66, said composite bone graft further comprising a first top surface and a second bottom surface, said first top surface and said second bottom surface comprising a plurality of protrusions defining a saw-tooth pattern **{Fig. 7 items 711A and 711B; Fig. 1D-E item 120}**.

72. A composite cervical wedge **{page 3 lines 7-8}**, comprising:

a first substantially planer cortical bone portion **{Fig. 7 item 711A}**;

a second substantially planer cortical bone portion provided on said first substantially planer cortical bone portion to form a graft unit **{Fig. 7 item 711B}**, said graft unit having a top

textured surface and a bottom textured surface **{Figs. 1D-E item 120; Fig. 7 items 711A and 711B}**;

one or more biocompatible mechanical connectors for holding together said graft unit **{page 18 line 27-page 19 line 6}**, said one or more biocompatible mechanical connectors are provided perpendicular to or parallel to an interface of said first substantially planer cortical bone portion and said second substantially planer cortical bone portion **{Fig. 7 items 711A and 711B}**; and

a through-hole entirely traversing said composite bone graft **{Figs. 1 and 7 item 104}**, said through-hole is disposed substantially perpendicular to interfaces of adjacent bone portions, forming said composite cervical wedge, said composite cervical wedge comprises:

a first width of from about 7 mm-14 mm **{page 6 lines 1-2; Figs. 6A-I; page 18 lines 8-17}**; a second width of from about 7 mm-14 mm **{page 6 lines 1-2; Figs. 6A-I; page 18 lines 8-17}**; a composite anterior height of from about 7 mm-14 mm **{page 5 lines 24-27; Figs. 6A-I; page 18 lines 8-17}**; a composite posterior height of from about 7 mm-14 mm **{page 5 lines 24-27; Figs. 6A-I; page 18 lines 8-17}**; and a diameter of from about 7 mm-14 mm **{page 6 line 1-2; claim 1}**, wherein said top textured surface and said bottom textured surface are opposing and are disposed parallel to interfaces of said bone portions **{Fig. 7 items 711A and 711B}**, said top textured surface and said bottom textured surface comprises a plurality of protrusions defining a saw-tooth pattern **{Fig. 7 items 711A and 711B}**, and wherein said composite bone graft does not comprise an adhesive.

73. A composite cervical block **{page 3 lines 7-8}**, comprising:

a first substantially planer cortical bone portion **{Fig. 7 item 711A}**;

a second substantially planer cortical bone portion provided on said first substantially planer cortical bone portion to form a graft unit **{Fig. 7 item 711B}**, said graft unit having a top textured surface and a bottom textured surface **{Figs. 1D-E item 120; Fig. 7 items 711A and 711B}**;

one or more biocompatible mechanical connectors for holding together said graft unit **{page 18 line 27-page 19 line 6}**, said one or more biocompatible mechanical connectors are provided perpendicular to or parallel to an interface of said first substantially planer cortical bone portion and said second substantially planer cortical bone portion **{Fig. 7 items 711A and 711B}**; and

a through-hole entirely traversing said composite bone graft **{Figs. 1 and 7 item 104}**, said through-hole is disposed substantially perpendicular to interfaces of adjacent bone portions **{Fig. 7 items 711A and 711B}**, forming said composite cervical wedge, said composite cervical wedge comprises:

a first width of from about 7 mm-14 mm **{page 6 lines 1-2; Figs. 6A-I; page 18 line 27-page 19 line 6}**; a second width of from about 7 mm-14 mm **{page 6 lines 1-2; Figs 6A-I; page 18 line 27-page 19 line 6}**; a composite height of from about 7 mm-14 mm **{page 5 lines 24-27; Figs. 6A-I; page 18 line 27-page 19 line 6}**; and a diameter of from about 7 mm-14 mm **{page 6 lines 1-2; claim 1}**, wherein said top textured surface and said bottom textured surface are opposing and are disposed parallel to interfaces of said bone portions **{Fig. 7 items 711A and 711B}**, said top textured surface and said bottom textured surface comprises a plurality of

protrusions defining a saw-tooth pattern **{Figs. 1D-E item 120; Fig. 7 items 711A and 711B}**, and wherein said composite bone graft does not comprise an adhesive.

74. The composite bone graft of any one of claims 60, 62, 64-66, 72, or 73, further comprising osteoinductive substances provided in said through-hole **{page 3 lines 4-7; page 24 lines 8-16}**, said osteoinductive substances are selected from the group consisting of demineralized bone and bone marrow cancellous bone **{page 24 lines 12-13}**.

75. The composite bone graft of claim 74, said osteoinductive substances further comprising one or more members selected from the group consisting of bone morphogenic protein and a growth factor **{page 19 lines 12-17 and page 24 lines 8-16}**.

76. The composite bone graft of claim 75, said through-hole has a diameter of from about 2.0 mm to about 8.0 mm **{Figs. 6A and 6D; page 6 lines 1-2}**.

77. The composite bone graft of any one of claims 59, 60, 62, 64-66, 72, or 73, said bone portions comprising allogenic bone **{page 3 lines 4-5}**.

78. The composite bone graft of claim 65, said two or more distinct, adjacent, bone portions comprise one or more members selected from the group consisting of cortical bone and cancellous bone **{page 4 lines 23-24 and page 6 line 28-page 7 line 3}**.

79. The composite bone graft of claim 78, said cortical bone and said cancellous bone, comprising allogenic bone **{page 3 lines 4-5}**.

80. The composite bone graft of claim 65, said composite bone graft further comprising a top surface; a bottom surface; a diameter of from about 7 mm-14 mm **{page 6 lines 1-2; Figs. 6A-I; page 18 line 27-page 19 line 6; claim 1}**; a width of from about 7 mm-14 mm **{page 6 lines 1-2; Figs. 6A-I; page 18 line 27-page 19 line 6}**; an anterior composite height of from about 7 mm-14 mm **{page 5 lines 24-27; Figs. 6A-I; page 18 line 27-page 19 line 6}**; and a posterior composite height of from about 7 mm-14 mm **{page 5 lines 24-27; Figs. 6A-I; page 18 line 27-page 19 line 6}**.

81. The composite bone graft of claim 80, said top surface and said bottom surface comprising a plurality of protrusions defining a saw-tooth pattern **{Figs. 1D-E item 120; Figs. 7 items 711A and 711B}**.

82. The composite bone graft of any one of claims 73 or 81, said plurality of protrusions having a height of about 4 mm **{Figs. 5C-5E; Fig. 6C; page 17 line 10-page 18 line 7}**.

83. The composite bone graft of any one of claims 60, 61, 66, 72, or 73, said first cortical bone portion comprises one or more cortical bone planks **{Fig. 7 item 711A; page 18 line 18-page 19 line 17}**, and said second cortical bone portion comprises one or more cortical bone planks **{Fig. 7 item 711B; page 18 line 20-page 19 line 17}**.

84. The composite bone graft of any one of claims 62-64 or 65, each of said cortical bone portions comprises one or more cortical bone planks **{Fig. 7 items 711A and 711B; page 18 line 20-page 19 line 17}**.

85. The composite bone graft of claim 71, said plurality of protrusions having a height of about 4 mm **{Figs. 5C-5E; Fig. 6C; page 17 line 10-page 18 line 7}**.

86. A composite bone graft **{page 18 lines 18-20}**, comprising:

a first cortical bone portion comprising one or more cortical bone planks **{Fig. 7; items 711A and 711B}**, and having a first face comprising protrusions **{Fig. 7 pins protrude from item 711A; page 18 line 27-page 19 line 6}**;

a second cortical bone portion comprising one or more cortical bone planks **{Fig. 7, item 711B}**, and having a second face comprising depressions **{Fig. 7 holes for pins in item 711A in item 711B}** complimentary to said protrusions provided on said first face, said second cortical bone portion is provided on said first cortical bone portion such that said first face and said second face interlock to form a graft unit **{Fig. 7 items 711A and 711B}**; and

a cortical bone locking pin located approximately parallel or perpendicular to the interface of said first cortical bone portion and said second cortical bone portion **{Fig. 7 items 711A and 711B; page 18 line 27-page 19 line 6}**, said cortical bone locking pin partially traverses said graft unit.

87. A composite bone graft **{page 18 lines 18-20}**, comprising:

a first substantially planer cortical bone portion **{Fig. 7 item 711A}**;

a second substantially planer cortical bone portion provided on said first substantially planer cortical bone portion to form a graft unit **{Fig. 7, item 711B}**;

one or more biocompatible mechanical connectors for holding together said graft unit **{page 18 line 27-page 19 line 6}**, said one or more biocompatible mechanical connectors are

provided perpendicular to or parallel to an interface of said first substantially planer cortical bone portion and said second substantially planer cortical bone portion; and

a through-hole entirely traversing said composite bone graft {**Figs. 1 and 7 item 104; Fig. 7 items 711A and 711B**}, said through-hole is disposed substantially perpendicular to interfaces of adjacent bone portion.

88. A composite bone graft {**page 18 lines 18-20**}, comprising:

two or more distinct, adjacent, cortical bone portions {**Fig. 7 items 711A and 711B**}, said distinct, adjacent, cortical bone portions each comprising a face complimentary to a face on an adjacent cortical bone portion, each face comprising projections or depressions, such that adjacent faces are complimentary, and a single projection interlocks with a single depression, to provide an interlocking fit between said adjacent bone portions {**Fig. 7 pins project from item 711A into depressions (i.e., holes) in item 711B**}; and

a through-hole entirely traversing said composite bone graft {**Figs. 1 and 7 item 104; Fig. 7 items 711A and 711B**}, said through-hole is disposed substantially perpendicular to interfaces of adjacent bone portions {**Fig. 7 items 711A and 711B**}.

89. A composite bone graft {**page 18 lines 18-20**}, comprising:

two or more distinct, adjacent, cortical bone portions {**Fig. 7 items 711A and 711B**), said distinct, adjacent, cortical bone portions each comprising a face complimentary to a face on an adjacent cortical bone portion, each face comprising projections or depressions, such that adjacent faces are complimentary, and a single projection interlocks with a single depression, to

provide an interlocking fit between said adjacent bone portions {**Fig. 7 pins project from item 711A into depressions in item 711B**};

one or more locking pins comprising cortical bone {**page 18 line 27-page 19 line 6**}, partially or entirely traversing a dimension of said composite bone graft, said one or more locking pins provided perpendicular to or parallel to an interface between adjacent bone portions {**Fig. 7 items 711A and 711B**}; and

a through-hole entirely traversing said composite bone graft {**Figs. 1 and 7 item 104**}, said through-hole is disposed substantially perpendicular to interfaces of said adjacent bone portions {**Fig. 7 items 711A and 711B**}.

90. A composite bone graft {**page 18 lines 18-20**}, comprising:

two or more distinct, adjacent, bone portions layered to form a graft unit {**Fig. 7 items 711A and 711B**}; one or more biocompatible mechanical connectors provided perpendicular to an interface between adjacent bone portions {**Fig. 7 items 711A and 711B; page 18 line 27-page 19 line 6**}; and a first chamfered edge {**Figs. 1D-E item 115**} and a second chamfered edge {**Figs. 1D-E item 115**}, said first chamfered edge provided along a length of said composite bone graft at its top edge {**Figs. 1C-D**}, and said second chamfered edge provided along a length of said composite bone graft at its bottom edge {**Figs. 1C-D**}, such that the chamfered edges are diametrically opposed {**Fig. 1C item 115**}; and

a through-hole entirely traversing said composite bone graft {**Figs. 1 and 7 item 104**}, said through-hole is disposed substantially perpendicular to interfaces of portions adjacent bone portion {**Fig. 7 items 711A and 711B**}.

91. A composite bone graft **{page 18 lines 18-20}**, comprising:

a first cortical bone portion **{Fig. 7 item 711A}**;

a second cortical bone portion provided on said first cortical bone portion to form a graft unit **{Fig. 7 item 711B}**;

one or more biocompatible mechanical connectors for holding together said graft unit **{page 18 line 27-page 19 line 6}**, said one or more biocompatible mechanical connectors are provided perpendicular to or parallel to an interface of said first cortical bone portion and said second cortical bone portion **{Fig. 7 items 711A and 711B}**; and

a through-hole entirely traversing said composite bone graft **{Figs. 1 and 7 item 104}**, said through-hole is disposed substantially perpendicular to interfaces of adjacent bone portions **{Fig. 7 items 711A and711B}**.

92. The composite bone graft of claim 91, said first cortical bone portion comprises one or more cortical bone planks **{Fig. 7 item 711A}**, and said second cortical bone portion comprises one or more cortical bone planks **{Fig. 7 item 711B}**.

93. The composite bone graft of claim 92, said first cortical bone portion comprises a first face comprising a protrusion and said second cortical bone portion comprises a second face comprising a depression complimentary to said first face, such that said first face and said second face interlock **{page 18 line 27-page 19 line 6}** wherein said composite bone graft does not comprise an adhesive.

94. The composite bone graft of claim 93, said one or more biocompatible mechanical connectors comprise a single cortical bone pin **{page 18 line 27-page 19 line 6}**.

95. The composite bone graft of claim 94, said cortical bone pin comprises a locking pin **{page 18 line 27-page 19 line 6}**, said locking pin partially traverses said graft unit and is located approximately parallel or perpendicular to the interface of said first cortical bone portion and said second cortical bone portion **{Fig. 7 items 711A and 711B}**.

96. The composite bone graft of any one of claims 87, 88, 89, 90, or 91, said composite bone graft further comprising a first top surface and a second bottom surface, said first top surface and said second bottom surface comprising a plurality of protrusions defining a saw-tooth pattern **{Fig. 7 items 711A and 711B; Fig. 1D-E item 120}**.

97. A composite cervical wedge **{page 3 lines 7-8}**, comprising:

a first substantially planer cortical bone portion **{Fig. 7 item 711A}**;

a second substantially planer cortical bone portion provided on said first substantially planer cortical bone portion to form a graft unit **{Fig. 7 item 711B}**, said graft unit having a top textured surface and a bottom textured surface **{Figs. 1D-E item 120; Fig. 7 items 711A and 711B}**;

one or more biocompatible mechanical connectors for holding together said graft unit **{page 18 line 27-page 19 line 6}**, said one or more biocompatible mechanical connectors are provided perpendicular to or parallel to an interface of said first substantially planer cortical bone

portion and said second substantially planer cortical bone portion **{Fig. 7 items 711A and 711B}**; and

a through-hole entirely traversing said composite bone graft **{Figs. 1 and 7 item 104}**, said through-hole is disposed substantially perpendicular to interfaces of adjacent bone portions, forming said composite cervical wedge, said composite cervical wedge comprises:

a first width of from about 7 mm-14 mm **{page 6 lines 1-2; Figs. 6A-I; page 18 lines 8-17}**; a second width of from about 7 mm-14 mm **{page 6 lines 1-2; Figs. 6A-I; page 18 lines 8-17}**; a composite anterior height of from about 7 mm-14 mm **{page 5 lines 24-27; Figs. 6A-I; page 18 lines 8-17}**; a composite posterior height of from about 7 mm-14 mm **{page 5 lines 24-27; Figs. 6A-I; page 18 lines 8-17}**; and a diameter of from about 7 mm-14 mm **{page 6 line 1-2; claim 1}**, wherein said top textured surface and said bottom textured surface are opposing and are disposed parallel to interfaces of said bone portions **{Fig. 7 items 711A and 711B}**, said top textured surface and said bottom textured surface comprises a plurality of protrusions defining a saw-tooth pattern **{Fig. 7 items 711A and 711B}**.

98. A composite cervical block **{page 3 lines 7-8}**, comprising:

a first substantially planer cortical bone portion **{Fig. 7 item 711A}**;

a second substantially planer cortical bone portion provided on said first substantially planer cortical bone portion to form a graft unit **{Fig. 7 item 711B}**, said graft unit having a top textured surface and a bottom textured surface **{Figs. 1D-E item 120; Fig. 7 items 711A and 711B}**;

one or more biocompatible mechanical connectors for holding together said graft unit **{page 18 line 27-page 19 line 6}**, said one or more biocompatible mechanical connectors are provided perpendicular to or parallel to an interface of said first substantially planer cortical bone portion and said second substantially planer cortical bone portion **{Fig. 7 items 711A and 711B}**; and

a through-hole entirely traversing said composite bone graft **{Figs. 1 and 7 item 104}**, said through-hole is disposed substantially perpendicular to interfaces of adjacent bone portions **{Fig. 7 items 711A and 711B}**, forming said composite cervical wedge, said composite cervical wedge comprises:

a first width of from about 7 mm-14 mm **{page 6 lines 1-2; Figs. 6A-I; page 18 line 27-page 19 line 6}**; a second width of from about 7 mm-14 mm **{page 6 lines 1-2; Figs 6A-I; page 18 line 27-page 19 line 6}**; a composite height of from about 7 mm-14 mm **{page 5 lines 24-27; Figs. 6A-I; page 18 line 27-page 19 line 6}**; and a diameter of from about 7 mm-14 mm **{page 6 lines 1-2; claim 1}**, wherein said top textured surface and said bottom textured surface are opposing and are disposed parallel to interfaces of said bone portions **{Fig. 7 items 711A and 711B}**, said top textured surface and said bottom textured surface comprises a plurality of protrusions defining a saw-tooth pattern **{Figs. 1D-E item 120; Fig. 7 items 711A and 711B}**.

99. The composite bone graft of any one of claims 87-91, 97, or 98, further comprising osteoinductive substances provided in said through-hole **{page 3 lines 4-7; page 24 lines 8-16}**, said osteoinductive substances are selected from the group consisting of demineralized bone and bone marrow cancellous bone **{page 24 lines 12-13}**.

100. The composite bone graft of claim 99, said osteoinductive substances further comprising one or more members selected from the group consisting of bone morphogenic protein and a growth factor **{page 19 lines 12-17 and page 24 lines 8-16}**.

101. The composite bone graft of claim 100, said through-hole has a diameter of from about 2.0 mm to about 8.0 mm **{Figs. 6A and 6D; page 6 lines 1-2}**.

102. The composite bone graft of any one of claims 86-91, 97, or 98, said bone portions comprising allogenic bone **{page 3 lines 4-5}**.

103. The composite bone graft of claim 90, said two or more distinct, adjacent, bone portions comprise one or more members selected from the group consisting of cortical bone and cancellous bone **{page 4 lines 23-24 and page 6 line 28-page 7 line 3}**.

104. The composite bone graft of claim 103, said cortical bone and said cancellous bone, comprising allogenic bone **{page 3 lines 4-5}**.

105. The composite bone graft of claim 90, said composite bone graft further comprising a top surface; a bottom surface; a diameter of from about 7 mm-14 mm **{page 6 lines 1-2; Figs. 6A-I; page 18 line 27-page 19 line 6; claim 1}**; a width of from about 7 mm-14 mm **{page 6 lines 1-2; Figs. 6A-I; page 18 line 27-page 19 line 6}**; an anterior composite height of from about 7 mm-14 mm **{page 5 lines 24-27; Figs. 6A-I; page 18 line 27-page 19 line 6}**; and a posterior composite height of from about 7 mm-14 mm **{page 5 lines 24-27; Figs. 6A-I; page 18 line 27-page 19 line 6}**.

106. The composite bone graft of claim 105, said top surface and said bottom surface comprising a plurality of protrusions defining a saw-tooth pattern **{Figs. 1D-E item 120; Figs. 7 items 711A and 711B}**.

107. The composite bone graft of any one of claims 98 or 106, said plurality of protrusions having a height of about 4 mm **{Figs. 5C-5E; Fig. 6C; page 17 line 10-page 18 line 7}**.

108. The composite bone graft of any one of claims 61, 87, 91, 97, or 98, said first cortical bone portion comprises one or more cortical bone planks **{Fig. 7 item 711A; page 18 line 18-page 19 line 17}**, and said second cortical bone portion comprises one or more cortical bone planks **{Fig. 7 item 711B; page 18 line 20-page 19 line 17}**.

109. The composite bone graft of any one of claims 63, 88, 89, or 90, each of said cortical bone portions comprises one or more cortical bone planks **{Fig. 7 items 711A and 711B; page 18 line 20-page 19 line 17}**.

110. The composite bone graft of claim 96, said plurality of protrusions having a height of about 4 mm **{Figs. 5C-5E; Fig. 6C; page 17 line 10-page 18 line 7}**.

VI. <u>37 CFR 1.607(a)(6)</u>

37 CFR 1.607(a)(6) is irrelevant since this request and the accompanying 37 CFR 1.607(a)(4) amendment are being submitted prior to one year from the date on which the Anderson et al. patent was granted.

VII. REQUEST FOR THE BENEFIT OF THE FILING DATES OF APPLICANTS' PRIORITY APPLICATIONS

Applicants claim priority under 35 USC 120 of application serial Nos. 08/920,630 filed 27 August 1997 and 09/701,933 (PCT/US98/17769) filed 27 August 1998.

Applicants are entitled to the benefit of the filing date of any of their earlier filed applications if the count reads on at least one adequately disclosed embodiment in the earlier application.[1] Assuming that the examiner recommends to the board applicants' proposed count, applicants clearly meet that standard. That this is so is demonstrated from the fact that this application is a continuation from application serial No. 09/701,933, which in turn is a continuation-in-part of application serial No. 08/920,630. Applicants' earlier filed application serial No. 09/701,933 is a 35 USC 371 U.S. national stage application based on international application PCT/US98/17769 filed 27 August 1998. Pursuant to 35 USC 363, the filing date of application serial No. 09/701,933 is the same as the filing date of international application PCT/US98/17769 -- namely, 27 August 1998. The PCT application was published as WO 99/09914 on 04 March 1999.

A. THE W0 99/09914 DISCLOSURE

The terms of application claims 59-110 corresponding to the proposed count can be applied to the disclosure of applications 09/701,933 and PCT/US98/17769 as published in WO 99/09914 as shown by the inserts in bold below as follows:

59. A composite bone graft **{page 16 lines 13-15}**, comprising:

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[1] Weil v. Fritz, 572 F.2d 856, 865-66 n.16, 196 USPQ 600, 608 n.16 (CCPA 1978).

a first cortical bone portion comprising one or more cortical bone planks **{Fig. 7; items 711A and 711B}**, and having a first face comprising protrusions **{Fig. 7 pins protrude from item 711A; page 16 lines 23-30}**;

a second cortical bone portion comprising one or more cortical bone planks **{Fig. 7, item 711B}**, and having a second face comprising depressions **{Fig. 7 holes for pins in item 711A in item 711B}** complimentary to said protrusions provided on said first face, said second cortical bone portion is provided on said first cortical bone portion such that said first face and said second face interlock to form a graft unit **{Fig. 7 items 711A and 711B}**; and

a cortical bone locking pin located approximately parallel or perpendicular to the interface of said first cortical bone portion and said second cortical bone portion **{Fig. 7 items 711A and 711B; page 16 lines 23-30}**, said cortical bone locking pin partially traverses said graft unit, wherein said composite bone graft does not comprise an adhesive.

60. A composite bone graft **{page 16 lines 13-15}**, comprising:

a first substantially planer cortical bone portion **{Fig. 7 item 711A}**;

a second substantially planer cortical bone portion provided on said first substantially planer cortical bone portion to form a graft unit **{Fig. 7, item 711B}**;

one or more biocompatible mechanical connectors for holding together said graft unit **{page 16 lines 23-30}**, said one or more biocompatible mechanical connectors are provided perpendicular to or parallel to an interface of said first substantially planer cortical bone portion and said second substantially planer cortical bone portion; and

a through-hole entirely traversing said composite bone graft **{Figs. 1 and 7 item 104; Fig. 7 items 711A and 711B}**, said through-hole is disposed substantially perpendicular to interfaces of adjacent bone portion, wherein said composite bone graft does not comprise an adhesive.

61. A composite bone graft **{page 16 lines 13-15}**, consisting essentially of:

a first substantially planer cortical bone portion **{Fig. 7 item 711A}**;

a second substantially planer cortical bone portion provided on said first substantially planer cortical bone portion to form a graft unit **{Fig. 7 item 711B}**;

one or more biocompatible mechanical connectors for holding together said graft unit **{page 16 lines 23-30}**, said one or more biocompatible mechanical connectors are provided perpendicular to or parallel to an interface of said first substantially planer cortical bone portion and said second substantially planer cortical bone portion; and

a through-hole entirely traversing said composite bone graft **{Figs. 1 and 7 item 104; Fig. 7 items 711A and 711B}**, said through-hole is disposed substantially perpendicular to interfaces of adjacent bone portions.

62. A composite bone graft **{page 16 lines 13-15}**, comprising:

two or more distinct, adjacent, cortical bone portions **{Fig. 7 items 711A and 711B}**, said distinct, adjacent, cortical bone portions each comprising a face complimentary to a face on an adjacent cortical bone portion, each face comprising projections or depressions, such that adjacent faces are complimentary, and a single projection interlocks with a single depression, to provide an interlocking fit between said adjacent bone portions **{Fig. 7 pins project from item 711A into depressions (i.e., holes) in item 711B}**; and

a through-hole entirely traversing said composite bone graft **{Figs. 1 and 7 item 104; Fig. 7 items 711A and 711B}**, said through-hole is disposed substantially perpendicular to interfaces of adjacent bone portions **{Fig. 7 items 711A and 711B}**, wherein said composite bone graft does not comprise an adhesive.

63. A composite bone graft **{page 16 lines 13-15}**, consisting essentially of:

two or more distinct, adjacent, cortical bone portions **{Fig. 7 items 711A and 711B}**, said distinct, adjacent, cortical bone portions each comprising a face complimentary to a face on an adjacent cortical bone portion, each face comprising projections or depressions, such that adjacent faces are complimentary, and a single projection interlocks with a single depression, to provide an interlocking fit between said adjacent bone portions **{Fig. 7 pins project from item 711A into depressions in item 711B}**;

one or more locking pins comprising cortical bone, partially or entirely traversing a dimension of said composite bone graft **{page 16 lines 23-30}**, said one or more locking pins provided perpendicular to or parallel to an interface between adjacent bone portions **{Fig. 7 items 711A and 711B}**, and

a through-hole entirely traversing said composite bone graft **{Figs. 1 and 7 item 104; Fig. 7 items 711A and 711B}**, said through-hole is disposed substantially perpendicular to interfaces of adjacent bone portions **{Fig. 7 items 711A and 711B}**.

64. A composite bone graft **{page 16 lines 13-15}**, comprising:

two or more distinct, adjacent, cortical bone portions **{Fig. 7 items 711A and 711B)**, said distinct, adjacent, cortical bone portions each comprising a face complimentary to a face on an

adjacent cortical bone portion, each face comprising projections or depressions, such that adjacent faces are complimentary, and a single projection interlocks with a single depression, to provide an interlocking fit between said adjacent bone portions **{Fig. 7 pins project from item 711A into depressions in item 711B}**;

one or more locking pins comprising cortical bone **{page 16 lines 23-30}**, partially or entirely traversing a dimension of said composite bone graft, said one or more locking pins provided perpendicular to or parallel to an interface between adjacent bone portions **{Fig. 7 items 711A and 711B}**; and

a through-hole entirely traversing said composite bone graft **{Figs. 1 and 7 item 104}**, said through-hole is disposed substantially perpendicular to interfaces of said adjacent bone portions **{Fig. 7 items 711A and 711B}**, wherein said composite bone graft does not comprise an adhesive.

65. A composite bone graft **{page 16 lines 13-15}**, comprising:

two or more distinct, adjacent, bone portions layered to form a graft unit **{Fig. 7 items 711A and 711B}**; one or more biocompatible mechanical connectors provided perpendicular to an interface between adjacent bone portions **{Fig. 7 items 711A and 711B; page 16 lines 23-30}**; and a first chamfered edge **{Figs. 1D-E item 115}** and a second chamfered edge **{Figs. 1D-E item 115}**, said first chamfered edge provided along a length of said composite bone graft at its top edge **{Figs. 1C-D}**, and said second chamfered edge provided along a length of said composite bone graft at its bottom edge **{Figs. 1C-D}**, such that the chamfered edges are diametrically opposed **{Fig. 1C item 115}**; and

a through-hole entirely traversing said composite bone graft **{Figs. 1 and 7 item 104}**, said through-hole is disposed substantially perpendicular to interfaces of portions adjacent bone portion **{Fig. 7 items 711A and 711B}**, wherein said composite bone graft does not comprise an adhesive.

66. A composite bone graft **{page 16 lines 13-15}**, comprising:

a first cortical bone portion **{Fig. 7 item 711A}**;

a second cortical bone portion provided on said first cortical bone portion to form a graft unit **{Fig. 7 item 711B}**;

one or more biocompatible mechanical connectors for holding together said graft unit **{page 16 lines 23-30}**, said one or more biocompatible mechanical connectors are provided perpendicular to or parallel to an interface of said first cortical bone portion and said second cortical bone portion **{Fig. 7 items 711A and 711B}**; and

a through-hole entirely traversing said composite bone graft **{Figs. 1 and 7 item 104}**, said through-hole is disposed substantially perpendicular to interfaces of adjacent bone portions **{Fig. 7 items 711A and711B}**, wherein said composite bone graft does not comprise an adhesive.

67. The composite bone graft of claim 66, said first cortical bone portion comprises one or more cortical bone planks **{Fig. 7 item 711A}**, and said second cortical bone portion comprises one or more cortical bone planks **{Fig. 7 item 711B}**.

68. The composite bone graft of claim 67, said first cortical bone portion comprises a first face comprising a protrusion and said second cortical bone portion comprises a second face comprising a depression complimentary to said first face, such that said first face and said second face interlock **{page 16 lines 23-30}** wherein said composite bone graft does not comprise an adhesive.

69. The composite bone graft of claim 68, said one or more biocompatible mechanical connectors comprise a single cortical bone pin **{page 16 lines 23-30}**.

70. The composite bone graft of claim 69, said cortical bone pin comprises a locking pin **{page 16 lines 23-30}**, said locking pin partially traverses said graft unit and is located approximately parallel or perpendicular to the interface of said first cortical bone portion and said second cortical bone portion **{Fig. 7 items 711A and 711B}**.

71. The composite bone graft of any one of claims 60, 62, 64, 65, or 66, said composite bone graft further comprising a first top surface and a second bottom surface, said first top surface and said second bottom surface comprising a plurality of protrusions defining a saw-tooth pattern **{Fig. 7 items 711A and 711B; Fig. 1D-E item 120}**.

72. A composite cervical wedge **{page 2 lines 24-25}**, comprising:

a first substantially planer cortical bone portion **{Fig. 7 item 711A}**;

a second substantially planer cortical bone portion provided on said first substantially planer cortical bone portion to form a graft unit **{Fig. 7 item 711B}**, said graft unit having a top

textured surface and a bottom textured surface **{Figs. 1D-E item 120; Fig. 7 items 711A and 711B}**;

one or more biocompatible mechanical connectors for holding together said graft unit **{page 16 lines 23-30}**, said one or more biocompatible mechanical connectors are provided perpendicular to or parallel to an interface of said first substantially planer cortical bone portion and said second substantially planer cortical bone portion **{Fig. 7 items 711A and 711B}**; and

a through-hole entirely traversing said composite bone graft **{Figs. 1 and 7 item 104}**, said through-hole is disposed substantially perpendicular to interfaces of adjacent bone portions, forming said composite cervical wedge, said composite cervical wedge comprises:

a first width of from about 7 mm-14 mm **{page 5 lines 6-8; Figs. 6A-I; page 16 lines 3-12}**; a second width of from about 7 mm-14 mm **{page 5 lines 6-8; Figs. 6A-I; page 16 lines 3-12}**; a composite anterior height of from about 7 mm-14 mm **{page 5 lines 1-3; Figs. 6A-I; page 16 lines 3-12}**; a composite posterior height of from about 7 mm-14 mm **{page 5 lines 1-3; Figs. 6A-I; page 16 lines 3-12}**; and a diameter of from about 7 mm-14 mm **{page 5 line 6-8; claim 1}**, wherein said top textured surface and said bottom textured surface are opposing and are disposed parallel to interfaces of said bone portions **{Fig. 7 items 711A and 711B}**, said top textured surface and said bottom textured surface comprises a plurality of protrusions defining a saw-tooth pattern **{Fig. 7 items 711A and 711B}**, and wherein said composite bone graft does not comprise an adhesive.

73. A composite cervical block **{page 2 lines 24-25}**, comprising:

a first substantially planer cortical bone portion **{Fig. 7 item 711A}**;

a second substantially planer cortical bone portion provided on said first substantially planer cortical bone portion to form a graft unit **{Fig. 7 item 711B}**, said graft unit having a top textured surface and a bottom textured surface **{Figs. 1D-E item 120; Fig. 7 items 711A and 711B}**;

one or more biocompatible mechanical connectors for holding together said graft unit **{page 16 lines 23-30}**, said one or more biocompatible mechanical connectors are provided perpendicular to or parallel to an interface of said first substantially planer cortical bone portion and said second substantially planer cortical bone portion **{Fig. 7 items 711A and 711B}**; and

a through-hole entirely traversing said composite bone graft **{Figs. 1 and 7 item 104}**, said through-hole is disposed substantially perpendicular to interfaces of adjacent bone portions **{Fig. 7 items 711A and 711B}**, forming said composite cervical wedge, said composite cervical wedge comprises:

a first width of from about 7 mm-14 mm **{page 5 lines 6-8; Figs. 6A-I; page 16 lines 23-30}**; a second width of from about 7 mm-14 mm **{page 5 lines 6-8; Figs 6A-I; page 16 lines 23-30}**; a composite height of from about 7 mm-14 mm **{page 5 lines 1-3; Figs. 6A-I; page 16 lines 23-30}**; and a diameter of from about 7 mm-14 mm **{page 5 lines 6-8; claim 1}**, wherein said top textured surface and said bottom textured surface are opposing and are disposed parallel to interfaces of said bone portions **{Fig. 7 items 711A and 711B}**, said top textured surface and said bottom textured surface comprises a plurality of protrusions defining a saw-tooth pattern **{Figs. 1D-E item 120; Fig. 7 items 711A and 711B}**, and wherein said composite bone graft does not comprise an adhesive.

74. The composite bone graft of any one of claims 60, 62, 64-66, 72, or 73, further comprising osteoinductive substances provided in said through-hole **{page 2 lines 20-24; page 21 line 18-page 22 line 6}**, said osteoinductive substances are selected from the group consisting of demineralized bone and bone marrow cancellous bone **{page 22 lines 3-5}**.

75. The composite bone graft of claim 74, said osteoinductive substances further comprising one or more members selected from the group consisting of bone morphogenic protein and a growth factor **{page 17 lines 4-8 and page 21 line 18-page 22 line 6}**.

76. The composite bone graft of claim 75, said through-hole has a diameter of from about 2.0 mm to about 8.0 mm **{Figs. 6A and 6D; page 5 lines 6-8}**.

77. The composite bone graft of any one of claims 59, 60, 62, 64-66, 72, or 73, said bone portions comprising allogenic bone **{page 2 lines 20-21}**.

78. The composite bone graft of claim 65, said two or more distinct, adjacent, bone portions comprise one or more members selected from the group consisting of cortical bone and cancellous bone **{page 4 lines 3-4 and page 6 lines 2-5}**.

79. The composite bone graft of claim 78, said cortical bone and said cancellous bone, comprising allogenic bone **{page 2 lines 20-21}**.

80. The composite bone graft of claim 65, said composite bone graft further comprising a top surface; a bottom surface; a diameter of from about 7 mm-14 mm **{page 5 lines 6-8; Figs. 6A-I; page 16 lines 23-30; claim 1}**; a width of from about 7 mm-14 mm **{page 5 lines 6-8; Figs. 6A-**

I; **page 16 lines 23-30}**; an anterior composite height of from about 7 mm-14 mm **{page 5 lines 1-3; Figs. 6A-I; page 16 lines 23-30}**; and a posterior composite height of from about 7 mm-14 mm **{page 5 lines 1-3; Figs. 6A-I; page 16 lines 23-30}**.

81. The composite bone graft of claim 80, said top surface and said bottom surface comprising a plurality of protrusions defining a saw-tooth pattern **{Figs. 1D-E item 120; Figs. 7 items 711A and 711B}**.

82. The composite bone graft of any one of claims 73 or 81, said plurality of protrusions having a height of about 4 mm **{Figs. 5C-5E; Fig. 6C; page 15 line 7-page 16 line 2}**.

83. The composite bone graft of any one of claims 60, 61, 66, 72, or 73, said first cortical bone portion comprises one or more cortical bone planks **{Fig. 7 item 711A; page 16 line 13-page 17 line 9}**, and said second cortical bone portion comprises one or more cortical bone planks **{Fig. 7 item 711B; page 17 lines 2-21}**.

84. The composite bone graft of any one of claims 62-64 or 65, each of said cortical bone portions comprises one or more cortical bone planks **{Fig. 7 items 711A and 711B; page 16 line 13-page 17 line 9}**.

85. The composite bone graft of claim 71, said plurality of protrusions having a height of about 4 mm **{Figs. 5C-5E; Fig. 6C; page 15 line 7-page 16 line 2}**.

86. A composite bone graft **{page 18 lines 18-20}**, comprising:

a first cortical bone portion comprising one or more cortical bone planks **{Fig. 7; items 711A and 711B}**, and having a first face comprising protrusions **{Fig. 7 pins protrude from item 711A; page 18 line 27-page 19 line 6}**;

a second cortical bone portion comprising one or more cortical bone planks **{Fig. 7, item 711B}**, and having a second face comprising depressions **{Fig. 7 holes for pins in item 711A in item 711B}** complimentary to said protrusions provided on said first face, said second cortical bone portion is provided on said first cortical bone portion such that said first face and said second face interlock to form a graft unit **{Fig. 7 items 711A and 711B}**; and

a cortical bone locking pin located approximately parallel or perpendicular to the interface of said first cortical bone portion and said second cortical bone portion **{Fig. 7 items 711A and 711B; page 18 line 27-page 19 line 6}**, said cortical bone locking pin partially traverses said graft unit.

87. A composite bone graft **{page 18 lines 18-20}**, comprising:

a first substantially planer cortical bone portion **{Fig. 7 item 711A}**;

a second substantially planer cortical bone portion provided on said first substantially planer cortical bone portion to form a graft unit **{Fig. 7, item 711B}**;

one or more biocompatible mechanical connectors for holding together said graft unit **{page 18 line 27-page 19 line 6}**, said one or more biocompatible mechanical connectors are provided perpendicular to or parallel to an interface of said first substantially planer cortical bone portion and said second substantially planer cortical bone portion; and

a through-hole entirely traversing said composite bone graft {**Figs. 1 and 7 item 104; Fig. 7 items 711A and 711B**}, said through-hole is disposed substantially perpendicular to interfaces of adjacent bone portion.

88. A composite bone graft {**page 18 lines 18-20**}, comprising:

two or more distinct, adjacent, cortical bone portions {**Fig. 7 items 711A and 711B**}, said distinct, adjacent, cortical bone portions each comprising a face complimentary to a face on an adjacent cortical bone portion, each face comprising projections or depressions, such that adjacent faces are complimentary, and a single projection interlocks with a single depression, to provide an interlocking fit between said adjacent bone portions {**Fig. 7 pins project from item 711A into depressions (i.e., holes) in item 711B**}; and

a through-hole entirely traversing said composite bone graft {**Figs. 1 and 7 item 104; Fig. 7 items 711A and 711B**}, said through-hole is disposed substantially perpendicular to interfaces of adjacent bone portions {**Fig. 7 items 711A and 711B**}.

89. A composite bone graft {**page 18 lines 18-20**}, comprising:

two or more distinct, adjacent, cortical bone portions {**Fig. 7 items 711A and 711B**), said distinct, adjacent, cortical bone portions each comprising a face complimentary to a face on an adjacent cortical bone portion, each face comprising projections or depressions, such that adjacent faces are complimentary, and a single projection interlocks with a single depression, to provide an interlocking fit between said adjacent bone portions {**Fig. 7 pins project from item 711A into depressions in item 711B**};

one or more locking pins comprising cortical bone **{page 18 line 27-page 19 line 6}**, partially or entirely traversing a dimension of said composite bone graft, said one or more locking pins provided perpendicular to or parallel to an interface between adjacent bone portions **{Fig. 7 items 711A and 711B}**; and

a through-hole entirely traversing said composite bone graft **{Figs. 1 and 7 item 104}**, said through-hole is disposed substantially perpendicular to interfaces of said adjacent bone portions **{Fig. 7 items 711A and 711B}**.

90. A composite bone graft **{page 18 lines 18-20}**, comprising:

two or more distinct, adjacent, bone portions layered to form a graft unit **{Fig. 7 items 711A and 711B}**; one or more biocompatible mechanical connectors provided perpendicular to an interface between adjacent bone portions **{Fig. 7 items 711A and 711B; page 18 line 27-page 19 line 6}**; and a first chamfered edge **{Figs. 1D-E item 115}** and a second chamfered edge **{Figs. 1D-E item 115}**, said first chamfered edge provided along a length of said composite bone graft at its top edge **{Figs. 1C-D}**, and said second chamfered edge provided along a length of said composite bone graft at its bottom edge **{Figs. 1C-D}**, such that the chamfered edges are diametrically opposed **{Fig. 1C item 115}**; and

a through-hole entirely traversing said composite bone graft **{Figs. 1 and 7 item 104}**, said through-hole is disposed substantially perpendicular to interfaces of portions adjacent bone portion **{Fig. 7 items 711A and 711B}**.

91. A composite bone graft **{page 18 lines 18-20}**, comprising:

a first cortical bone portion **{Fig. 7 item 711A}**;

a second cortical bone portion provided on said first cortical bone portion to form a graft unit **{Fig. 7 item 711B}**;

one or more biocompatible mechanical connectors for holding together said graft unit **{page 18 line 27-page 19 line 6}**, said one or more biocompatible mechanical connectors are provided perpendicular to or parallel to an interface of said first cortical bone portion and said second cortical bone portion **{Fig. 7 items 711A and 711B}**; and

a through-hole entirely traversing said composite bone graft **{Figs. 1 and 7 item 104}**, said through-hole is disposed substantially perpendicular to interfaces of adjacent bone portions **{Fig. 7 items 711A and711B}**.

92. The composite bone graft of claim 91, said first cortical bone portion comprises one or more cortical bone planks **{Fig. 7 item 711A}**, and said second cortical bone portion comprises one or more cortical bone planks **{Fig. 7 item 711B}**.

93. The composite bone graft of claim 92, said first cortical bone portion comprises a first face comprising a protrusion and said second cortical bone portion comprises a second face comprising a depression complimentary to said first face, such that said first face and said second face interlock **{page 18 line 27-page 19 line 6}** wherein said composite bone graft does not comprise an adhesive.

94. The composite bone graft of claim 93, said one or more biocompatible mechanical connectors comprise a single cortical bone pin **{page 18 line 27-page 19 line 6}**.

95. The composite bone graft of claim 94, said cortical bone pin comprises a locking pin **{page 18 line 27-page 19 line 6}**, said locking pin partially traverses said graft unit and is located approximately parallel or perpendicular to the interface of said first cortical bone portion and said second cortical bone portion **{Fig. 7 items 711A and 711B}**.

96. The composite bone graft of any one of claims 87, 88, 89, 90, or 91, said composite bone graft further comprising a first top surface and a second bottom surface, said first top surface and said second bottom surface comprising a plurality of protrusions defining a saw-tooth pattern **{Fig. 7 items 711A and 711B; Fig. 1D-E item 120}**.

97. A composite cervical wedge **{page 3 lines 7-8}**, comprising:

a first substantially planer cortical bone portion **{Fig. 7 item 711A}**;

a second substantially planer cortical bone portion provided on said first substantially planer cortical bone portion to form a graft unit **{Fig. 7 item 711B}**, said graft unit having a top textured surface and a bottom textured surface **{Figs. 1D-E item 120; Fig. 7 items 711A and 711B}**;

one or more biocompatible mechanical connectors for holding together said graft unit **{page 18 line 27-page 19 line 6}**, said one or more biocompatible mechanical connectors are provided perpendicular to or parallel to an interface of said first substantially planer cortical bone portion and said second substantially planer cortical bone portion **{Fig. 7 items 711A and 711B}**; and

a through-hole entirely traversing said composite bone graft **{Figs. 1 and 7 item 104}**, said through-hole is disposed substantially perpendicular to interfaces of adjacent bone portions, forming said composite cervical wedge, said composite cervical wedge comprises:

a first width of from about 7 mm-14 mm **{page 6 lines 1-2; Figs. 6A-I; page 18 lines 8-17}**; a second width of from about 7 mm-14 mm **{page 6 lines 1-2; Figs. 6A-I; page 18 lines 8-17}**; a composite anterior height of from about 7 mm-14 mm **{page 5 lines 24-27; Figs. 6A-I; page 18 lines 8-17}**; a composite posterior height of from about 7 mm-14 mm **{page 5 lines 24-27; Figs. 6A-I; page 18 lines 8-17}**; and a diameter of from about 7 mm-14 mm **{page 6 line 1-2; claim 1}**, wherein said top textured surface and said bottom textured surface are opposing and are disposed parallel to interfaces of said bone portions **{Fig. 7 items 711A and 711B}**, said top textured surface and said bottom textured surface comprises a plurality of protrusions defining a saw-tooth pattern **{Fig. 7 items 711A and 711B}**.

98. A composite cervical block **{page 3 lines 7-8}**, comprising:

a first substantially planer cortical bone portion **{Fig. 7 item 711A}**;

a second substantially planer cortical bone portion provided on said first substantially planer cortical bone portion to form a graft unit **{Fig. 7 item 711B}**, said graft unit having a top textured surface and a bottom textured surface **{Figs. 1D-E item 120; Fig. 7 items 711A and 711B}**;

one or more biocompatible mechanical connectors for holding together said graft unit **{page 18 line 27-page 19 line 6}**, said one or more biocompatible mechanical connectors are provided perpendicular to or parallel to an interface of said first substantially planer cortical bone

portion and said second substantially planer cortical bone portion **{Fig. 7 items 711A and 711B}**; and

a through-hole entirely traversing said composite bone graft **{Figs. 1 and 7 item 104}**, said through-hole is disposed substantially perpendicular to interfaces of adjacent bone portions **{Fig. 7 items 711A and 711B}**, forming said composite cervical wedge, said composite cervical wedge comprises:

a first width of from about 7 mm-14 mm **{page 6 lines 1-2; Figs. 6A-I; page 18 line 27-page 19 line 6}**; a second width of from about 7 mm-14 mm **{page 6 lines 1-2; Figs 6A-I; page 18 line 27-page 19 line 6}**; a composite height of from about 7 mm-14 mm **{page 5 lines 24-27; Figs. 6A-I; page 18 line 27-page 19 line 6}**; and a diameter of from about 7 mm-14 mm **{page 6 lines 1-2; claim 1}**, wherein said top textured surface and said bottom textured surface are opposing and are disposed parallel to interfaces of said bone portions **{Fig. 7 items 711A and 711B}**, said top textured surface and said bottom textured surface comprises a plurality of protrusions defining a saw-tooth pattern **{Figs. 1D-E item 120; Fig. 7 items 711A and 711B}**.

99. The composite bone graft of any one of claims 87-91, 97, or 98, further comprising osteoinductive substances provided in said through-hole **{page 3 lines 4-7; page 24 lines 8-16}**, said osteoinductive substances are selected from the group consisting of demineralized bone and bone marrow cancellous bone **{page 24 lines 12-13}**.

100. The composite bone graft of claim 99, said osteoinductive substances further comprising one or more members selected from the group consisting of bone morphogenic protein and a growth factor **{page 19 lines 12-17 and page 24 lines 8-16}**.

101. The composite bone graft of claim 100, said through-hole has a diameter of from about 2.0 mm to about 8.0 mm **{Figs. 6A and 6D; page 6 lines 1-2}**.

102. The composite bone graft of any one of claims 86-91, 97, or 98, said bone portions comprising allogenic bone **{page 3 lines 4-5}**.

103. The composite bone graft of claim 90, said two or more distinct, adjacent, bone portions comprise one or more members selected from the group consisting of cortical bone and cancellous bone **{page 4 lines 23-24 and page 6 line 28-page 7 line 3}**.

104. The composite bone graft of claim 103, said cortical bone and said cancellous bone, comprising allogenic bone **{page 3 lines 4-5}**.

105. The composite bone graft of claim 90, said composite bone graft further comprising a top surface; a bottom surface; a diameter of from about 7 mm-14 mm **{page 6 lines 1-2; Figs. 6A-I; page 18 line 27-page 19 line 6; claim 1}**; a width of from about 7 mm-14 mm **{page 6 lines 1-2; Figs. 6A-I; page 18 line 27-page 19 line 6}**; an anterior composite height of from about 7 mm-14 mm **{page 5 lines 24-27; Figs. 6A-I; page 18 line 27-page 19 line 6}**; and a posterior composite height of from about 7 mm-14 mm **{page 5 lines 24-27; Figs. 6A-I; page 18 line 27-page 19 line 6}**.

106. The composite bone graft of claim 105, said top surface and said bottom surface comprising a plurality of protrusions defining a saw-tooth pattern **{Figs. 1D-E item 120; Figs. 7 items 711A and 711B}**.

107. The composite bone graft of any one of claims 98 or 106, said plurality of protrusions having a height of about 4 mm **{Figs. 5C-5E; Fig. 6C; page 17 line 10-page 18 line 7}**.

108. The composite bone graft of any one of claims 61, 87, 91, 97, or 98, said first cortical bone portion comprises one or more cortical bone planks **{Fig. 7 item 711A; page 18 line 18-page 19 line 17}**, and said second cortical bone portion comprises one or more cortical bone planks **{Fig. 7 item 711B; page 18 line 20-page 19 line 17}**.

109. The composite bone graft of any one of claims 63, 88, 89, or 90, each of said cortical bone portions comprises one or more cortical bone planks **{Fig. 7 items 711A and 711B; page 18 line 20-page 19 line 17}**.

110. The composite bone graft of claim 96, said plurality of protrusions having a height of about 4 mm **{Figs. 5C-5E; Fig. 6C; page 17 line 10-page 18 line 7}**.

B. APPLICATION SERIAL NO. 08/920,630 DISCLOSURE

The terms of application claims 59-110 corresponding to the proposed count can be applied to the disclosure of application serial No. 08/920,630 as shown by the inserts in bold below as follows:

59. A composite bone graft **{page 16 line 29-page 17 line 2}**, comprising:

a first cortical bone portion comprising one or more cortical bone planks **{Fig. 7; items 711A and 711B}**, and having a first face comprising protrusions **{Fig. 7 pins protrude from item 711A; page 17 lines 10-17}**;

a second cortical bone portion comprising one or more cortical bone planks **{Fig. 7, item 711B}**, and having a second face comprising depressions **{Fig. 7 holes for pins in item 711A in item 711B}** complimentary to said protrusions provided on said first face, said second cortical bone portion is provided on said first cortical bone portion such that said first face and said second face interlock to form a graft unit **{Fig. 7 items 711A and 711B}**; and

a cortical bone locking pin located approximately parallel or perpendicular to the interface of said first cortical bone portion and said second cortical bone portion **{Fig. 7 items 711A and 711B; page 17 lines 10-17}**, said cortical bone locking pin partially traverses said graft unit, wherein said composite bone graft does not comprise an adhesive.

60. A composite bone graft **{page 16 line 29-page 17 line 2}**, comprising:

a first substantially planer cortical bone portion **{Fig. 7 item 711A}**;

a second substantially planer cortical bone portion provided on said first substantially planer cortical bone portion to form a graft unit **{Fig. 7, item 711B}**;

one or more biocompatible mechanical connectors for holding together said graft unit **{page 17 lines 10-17}**, said one or more biocompatible mechanical connectors are provided perpendicular to or parallel to an interface of said first substantially planer cortical bone portion and said second substantially planer cortical bone portion; and

a through-hole entirely traversing said composite bone graft **{Figs. 1 and 7 item 104; Fig. 7 items 711A and 711B}**, said through-hole is disposed substantially perpendicular to interfaces of adjacent bone portion, wherein said composite bone graft does not comprise an adhesive.

61. A composite bone graft **{page 16 line 29-page 17 line 2}**, consisting essentially of:

a first substantially planer cortical bone portion **{Fig. 7 item 711A}**;

a second substantially planer cortical bone portion provided on said first substantially planer cortical bone portion to form a graft unit **{Fig. 7 item 711B}**;

one or more biocompatible mechanical connectors for holding together said graft unit **{page 17 lines10-17}**, said one or more biocompatible mechanical connectors are provided perpendicular to or parallel to an interface of said first substantially planer cortical bone portion and said second substantially planer cortical bone portion; and

a through-hole entirely traversing said composite bone graft **{Figs. 1 and 7 item 104; Fig. 7 items 711A and 711B}**, said through-hole is disposed substantially perpendicular to interfaces of adjacent bone portions.

62. A composite bone graft **{page 16 line 29-page 17 line 2}**, comprising:

two or more distinct, adjacent, cortical bone portions **{Fig. 7 items 711A and 711B}**, said distinct, adjacent, cortical bone portions each comprising a face complimentary to a face on an adjacent cortical bone portion, each face comprising projections or depressions, such that adjacent faces are complimentary, and a single projection interlocks with a single depression, to provide an interlocking fit between said adjacent bone portions **{Fig. 7 pins project from item 711A into depressions (i.e., holes) in item 711B}**; and

a through-hole entirely traversing said composite bone graft **{Figs. 1 and 7 item 104; Fig. 7 items 711A and 711B}**, said through-hole is disposed substantially perpendicular to interfaces of adjacent bone portions **{Fig. 7 items 711A and 711B}**, wherein said composite bone graft does not comprise an adhesive.

63. A composite bone graft **{page 16 line 29-page 17 line 2}**, consisting essentially of:

two or more distinct, adjacent, cortical bone portions **{Fig. 7 items 711A and 711B}**, said distinct, adjacent, cortical bone portions each comprising a face complimentary to a face on an adjacent cortical bone portion, each face comprising projections or depressions, such that adjacent faces are complimentary, and a single projection interlocks with a single depression, to provide an interlocking fit between said adjacent bone portions **{Fig. 7 pins project from item 711A into depressions in item 711B}**;

one or more locking pins comprising cortical bone, partially or entirely traversing a dimension of said composite bone graft **{page 17 lines 10-17}**, said one or more locking pins provided perpendicular to or parallel to an interface between adjacent bone portions **{Fig. 7 items 711A and 711B}**, and

a through-hole entirely traversing said composite bone graft **{Figs. 1 and 7 item 104; Fig. 7 items 711A and 711B}**, said through-hole is disposed substantially perpendicular to interfaces of adjacent bone portions **{Fig. 7 items 711A and 711B}**.

64. A composite bone graft **{page 16 line 29-page 17 line 2}**, comprising:

two or more distinct, adjacent, cortical bone portions **{Fig. 7 items 711A and 711B)**, said distinct, adjacent, cortical bone portions each comprising a face complimentary to a face on an adjacent cortical bone portion, each face comprising projections or depressions, such that adjacent faces are complimentary, and a single projection interlocks with a single depression, to provide an interlocking fit between said adjacent bone portions **{Fig. 7 pins project from item 711A into depressions in item 711B}**;

one or more locking pins comprising cortical bone **{page 17 lines 10-17}**, partially or entirely traversing a dimension of said composite bone graft, said one or more locking pins provided perpendicular to or parallel to an interface between adjacent bone portions **{Fig. 7 items 711A and 711B}**; and

a through-hole entirely traversing said composite bone graft **{Figs. 1 and 7 item 104}**, said through-hole is disposed substantially perpendicular to interfaces of said adjacent bone portions **{Fig. 7 items 711A and 711B}**, wherein said composite bone graft does not comprise an adhesive.

65. A composite bone graft **{page 16 line 29-page 17 line 2}**, comprising:

two or more distinct, adjacent, bone portions layered to form a graft unit **{Fig. 7 items 711A and 711B}**; one or more biocompatible mechanical connectors provided perpendicular to an interface between adjacent bone portions **{Fig. 7 items 711A and 711B; page 17 lines 10-17}**; and a first chamfered edge **{Figs. 1D-E item 115}** and a second chamfered edge **{Figs. 1D-E item 115}**, said first chamfered edge provided along a length of said composite bone graft at its top edge **{Figs. 1C-D}**, and said second chamfered edge provided along a length of said composite bone graft at its bottom edge **{Figs. 1C-D}**, such that the chamfered edges are diametrically opposed **{Fig. 1C item 115}**; and

a through-hole entirely traversing said composite bone graft **{Figs. 1 and 7 item 104}**, said through-hole is disposed substantially perpendicular to interfaces of portions adjacent bone portion **{Fig. 7 items 711A and 711B}**, wherein said composite bone graft does not comprise an adhesive.

66. A composite bone graft **{page 16 line 29-page 17 line 2}**, comprising:

a first cortical bone portion **{Fig. 7 item 711A}**;

a second cortical bone portion provided on said first cortical bone portion to form a graft unit **{Fig. 7 item 711B}**;

one or more biocompatible mechanical connectors for holding together said graft unit **{page 17 lines 10-17}**, said one or more biocompatible mechanical connectors are provided perpendicular to or parallel to an interface of said first cortical bone portion and said second cortical bone portion **{Fig. 7 items 711A and 711B}**; and

a through-hole entirely traversing said composite bone graft **{Figs. 1 and 7 item 104}**, said through-hole is disposed substantially perpendicular to interfaces of adjacent bone portions **{Fig. 7 items 711A and711B}**, wherein said composite bone graft does not comprise an adhesive.

67. The composite bone graft of claim 66, said first cortical bone portion comprises one or more cortical bone planks **{Fig. 7 item 711A}**, and said second cortical bone portion comprises one or more cortical bone planks **{Fig. 7 item 711B}**.

68. The composite bone graft of claim 67, said first cortical bone portion comprises a first face comprising a protrusion and said second cortical bone portion comprises a second face comprising a depression complimentary to said first face, such that said first face and said second face interlock **{page 17 lines 10-17}** wherein said composite bone graft does not comprise an adhesive.

69. The composite bone graft of claim 68, said one or more biocompatible mechanical connectors comprise a single cortical bone pin **{page 17 lines 10-17}**.

70. The composite bone graft of claim 69, said cortical bone pin comprises a locking pin **{page 17 lines 10-17}**, said locking pin partially traverses said graft unit and is located approximately parallel or perpendicular to the interface of said first cortical bone portion and said second cortical bone portion **{Fig. 7 items 711A and 711B}**.

71. The composite bone graft of any one of claims 60, 62, 64, 65, or 66, said composite bone graft further comprising a first top surface and a second bottom surface, said first top surface and said second bottom surface comprising a plurality of protrusions defining a saw-tooth pattern **{Fig. 7 items 711A and 711B; Fig. 1D-E item 120}**.

72. A composite cervical wedge **{page 2 lines 23-25}**, comprising:

a first substantially planer cortical bone portion **{Fig. 7 item 711A}**;

a second substantially planer cortical bone portion provided on said first substantially planer cortical bone portion to form a graft unit **{Fig. 7 item 711B}**, said graft unit having a top textured surface and a bottom textured surface **{Figs. 1D-E item 120; Fig. 7 items 711A and 711B}**;

one or more biocompatible mechanical connectors for holding together said graft unit **{page 17 lines 10-17}**, said one or more biocompatible mechanical connectors are provided perpendicular to or parallel to an interface of said first substantially planer cortical bone portion and said second substantially planer cortical bone portion **{Fig. 7 items 711A and 711B}**; and

a through-hole entirely traversing said composite bone graft **{Figs. 1 and 7 item 104}**, said through-hole is disposed substantially perpendicular to interfaces of adjacent bone portions, forming said composite cervical wedge, said composite cervical wedge comprises:

a first width of from about 7 mm-14 mm **{page 5 lines 6-8; Figs. 6A-I; page 16 lines 19-28}**; a second width of from about 7 mm-14 mm **{page 5 lines 6-8; Figs. 6A-I; page 16 lines 19-28}**; a composite anterior height of from about 7 mm-14 mm **{page 5 lines 1-3; Figs. 6A-I; page 16 lines 19-28}**; a composite posterior height of from about 7 mm-14 mm **{page 5 lines 1-3 Figs. 6A-I; page 16 lines 19-28}**; and a diameter of from about 7 mm-14 mm **{page 5 line 6-8; claim 1}**, wherein said top textured surface and said bottom textured surface are opposing and are disposed parallel to interfaces of said bone portions **{Fig. 7 items 711A and 711B}**, said top textured surface and said bottom textured surface comprises a plurality of protrusions defining a saw-tooth pattern **{Fig. 7 items 711A and 711B}**, and wherein said composite bone graft does not comprise an adhesive.

73. A composite cervical block **{page 2 lines 23-25}**, comprising:

a first substantially planer cortical bone portion **{Fig. 7 item 711A}**;

a second substantially planer cortical bone portion provided on said first substantially planer cortical bone portion to form a graft unit **{Fig. 7 item 711B}**, said graft unit having a top textured surface and a bottom textured surface **{Figs. 1D-E item 120; Fig. 7 items 711A and 711B}**;

one or more biocompatible mechanical connectors for holding together said graft unit **{page 17 lines 10-17}**, said one or more biocompatible mechanical connectors are provided

perpendicular to or parallel to an interface of said first substantially planer cortical bone portion and said second substantially planer cortical bone portion **{Fig. 7 items 711A and 711B}**; and

a through-hole entirely traversing said composite bone graft **{Figs. 1 and 7 item 104}**, said through-hole is disposed substantially perpendicular to interfaces of adjacent bone portions **{Fig. 7 items 711A and 711B}**, forming said composite cervical wedge, said composite cervical wedge comprises:

a first width of from about 7 mm-14 mm **{page 5 lines 6-8; Figs. 6A-I; page 16 lines 19-28}**; a second width of from about 7 mm-14 mm **{page 5 lines 6-8; Figs 6A-I; page 16 lines 19-28}**; a composite height of from about 7 mm-14 mm **{page 5 lines 1-3; Figs. 6A-I; page 16 lines 19-28}**; and a diameter of from about 7 mm-14 mm **{page 5 lines 6-8; claim 1}**, wherein said top textured surface and said bottom textured surface are opposing and are disposed parallel to interfaces of said bone portions **{Fig. 7 items 711A and 711B}**, said top textured surface and said bottom textured surface comprises a plurality of protrusions defining a saw-tooth pattern **{Figs. 1D-E item 120; Fig. 7 items 711A and 711B}**, and wherein said composite bone graft does not comprise an adhesive.

74. The composite bone graft of any one of claims 60, 62, 64-66, 72, or 73, further comprising osteoinductive substances provided in said through-hole **{page 2 lines 21-23; page 18 lines 21-27}**, said osteoinductive substances are selected from the group consisting of demineralized bone and bone marrow cancellous bone **{page 18 lines 23-25}**.

75. The composite bone graft of claim 74, said osteoinductive substances further comprising one or more members selected from the group consisting of bone morphogenic protein and a growth factor **{page 18 line 26}**.

76. The composite bone graft of claim 75, said through-hole has a diameter of from about 2.0 mm to about 8.0 mm **{Figs. 6A and 6D; page 5 lines 6-8}**.

77. The composite bone graft of any one of claims 59, 60, 62, 64-66, 72, or 73, said bone portions comprising allogenic bone **{page 2 lines 21-22}**.

78. The composite bone graft of claim 65, said two or more distinct, adjacent, bone portions comprise one or more members selected from the group consisting of cortical bone and cancellous bone **{page 3 line 29-page 4 line 1 and page 5 lines 26-29}**.

79. The composite bone graft of claim 78, said cortical bone and said cancellous bone, comprising allogenic bone **{page 2 lines 21-22}**.

80. The composite bone graft of claim 65, said composite bone graft further comprising a top surface; a bottom surface; a diameter of from about 7 mm-14 mm **{page 5 lines 6-8; Figs. 6A-I; page 16 lines 19-28; claim 1}**; a width of from about 7 mm-14 mm **{page 5 lines 6-8; Figs. 6A-I; page 16 lines 19-28}**; an anterior composite height of from about 7 mm-14 mm **{page 5 lines 1-3; Figs. 6A-I; page 16 lines 19-28}**; and a posterior composite height of from about 7 mm-14 mm **{page 5 lines 1-3; Figs. 6A-I; page 16 lines 19-28}**.

81. The composite bone graft of claim 80, said top surface and said bottom surface comprising a plurality of protrusions defining a saw-tooth pattern **{Figs. 1D-E item 120; Figs. 7 items 711A and 711B}**.

82. The composite bone graft of any one of claims 73 or 81, said plurality of protrusions having a height of about 4 mm **{Figs. 5C-5E; Fig. 6C; page 15 line 21-page 16 line 18}**.

83. The composite bone graft of any one of claims 60, 61, 66, 72, or 73, said first cortical bone portion comprises one or more cortical bone planks **{Fig. 7 item 711A; page 17 lines 2-21}**, and said second cortical bone portion comprises one or more cortical bone planks **{Fig. 7 item 711B; page 17 lines 2-21}**.

84. The composite bone graft of any one of claims 62-64 or 65, each of said cortical bone portions comprises one or more cortical bone planks **{Fig. 7 items 711A and 711B; page 17 lines 2-21}**.

85. The composite bone graft of claim 71, said plurality of protrusions having a height of about 4 mm **{Figs. 5C-5E; Fig. 6C; page 15 line 21-page 16 line 18}**.

86. A composite bone graft **{page 18 lines 18-20}**, comprising:

a first cortical bone portion comprising one or more cortical bone planks **{Fig. 7; items 711A and 711B}**, and having a first face comprising protrusions **{Fig. 7 pins protrude from item 711A; page 18 line 27-page 19 line 6}**;

a second cortical bone portion comprising one or more cortical bone planks **{Fig. 7, item 711B}**, and having a second face comprising depressions **{Fig. 7 holes for pins in item 711A in**

item 711B} complimentary to said protrusions provided on said first face, said second cortical bone portion is provided on said first cortical bone portion such that said first face and said second face interlock to form a graft unit **{Fig. 7 items 711A and 711B}**; and

a cortical bone locking pin located approximately parallel or perpendicular to the interface of said first cortical bone portion and said second cortical bone portion **{Fig. 7 items 711A and 711B; page 18 line 27-page 19 line 6}**, said cortical bone locking pin partially traverses said graft unit.

87. A composite bone graft **{page 18 lines 18-20}**, comprising:

a first substantially planer cortical bone portion **{Fig. 7 item 711A}**;

a second substantially planer cortical bone portion provided on said first substantially planer cortical bone portion to form a graft unit **{Fig. 7, item 711B}**;

one or more biocompatible mechanical connectors for holding together said graft unit **{page 18 line 27-page 19 line 6}**, said one or more biocompatible mechanical connectors are provided perpendicular to or parallel to an interface of said first substantially planer cortical bone portion and said second substantially planer cortical bone portion; and

a through-hole entirely traversing said composite bone graft **{Figs. 1 and 7 item 104; Fig. 7 items 711A and 711B}**, said through-hole is disposed substantially perpendicular to interfaces of adjacent bone portion.

88. A composite bone graft **{page 18 lines 18-20}**, comprising:

two or more distinct, adjacent, cortical bone portions **{Fig. 7 items 711A and 711B}**, said distinct, adjacent, cortical bone portions each comprising a face complimentary to a face on an

adjacent cortical bone portion, each face comprising projections or depressions, such that adjacent faces are complimentary, and a single projection interlocks with a single depression, to provide an interlocking fit between said adjacent bone portions {**Fig. 7 pins project from item 711A into depressions (i.e., holes) in item 711B**}; and

a through-hole entirely traversing said composite bone graft {**Figs. 1 and 7 item 104; Fig. 7 items 711A and 711B**}, said through-hole is disposed substantially perpendicular to interfaces of adjacent bone portions {**Fig. 7 items 711A and 711B**}.

89. A composite bone graft {**page 18 lines 18-20**}, comprising:

two or more distinct, adjacent, cortical bone portions {**Fig. 7 items 711A and 711B**), said distinct, adjacent, cortical bone portions each comprising a face complimentary to a face on an adjacent cortical bone portion, each face comprising projections or depressions, such that adjacent faces are complimentary, and a single projection interlocks with a single depression, to provide an interlocking fit between said adjacent bone portions {**Fig. 7 pins project from item 711A into depressions in item 711B**};

one or more locking pins comprising cortical bone {**page 18 line 27-page 19 line 6**}, partially or entirely traversing a dimension of said composite bone graft, said one or more locking pins provided perpendicular to or parallel to an interface between adjacent bone portions {**Fig. 7 items 711A and 711B**}; and

a through-hole entirely traversing said composite bone graft {**Figs. 1 and 7 item 104**}, said through-hole is disposed substantially perpendicular to interfaces of said adjacent bone portions {**Fig. 7 items 711A and 711B**}.

90. A composite bone graft **{page 18 lines 18-20}**, comprising:

two or more distinct, adjacent, bone portions layered to form a graft unit **{Fig. 7 items 711A and 711B}**; one or more biocompatible mechanical connectors provided perpendicular to an interface between adjacent bone portions **{Fig. 7 items 711A and 711B; page 18 line 27-page 19 line 6}**; and a first chamfered edge **{Figs. 1D-E item 115}** and a second chamfered edge **{Figs. 1D-E item 115}**, said first chamfered edge provided along a length of said composite bone graft at its top edge **{Figs. 1C-D}**, and said second chamfered edge provided along a length of said composite bone graft at its bottom edge **{Figs. 1C-D}**, such that the chamfered edges are diametrically opposed **{Fig. 1C item 115}**; and

a through-hole entirely traversing said composite bone graft **{Figs. 1 and 7 item 104}**, said through-hole is disposed substantially perpendicular to interfaces of portions adjacent bone portion **{Fig. 7 items 711A and 711B}**.

91. A composite bone graft **{page 18 lines 18-20}**, comprising:

a first cortical bone portion **{Fig. 7 item 711A}**;

a second cortical bone portion provided on said first cortical bone portion to form a graft unit **{Fig. 7 item 711B}**;

one or more biocompatible mechanical connectors for holding together said graft unit **{page 18 line 27-page 19 line 6}**, said one or more biocompatible mechanical connectors are provided perpendicular to or parallel to an interface of said first cortical bone portion and said second cortical bone portion **{Fig. 7 items 711A and 711B}**; and

a through-hole entirely traversing said composite bone graft **{Figs. 1 and 7 item 104}**, said through-hole is disposed substantially perpendicular to interfaces of adjacent bone portions **{Fig. 7 items 711A and711B}**.

92. The composite bone graft of claim 91, said first cortical bone portion comprises one or more cortical bone planks **{Fig. 7 item 711A}**, and said second cortical bone portion comprises one or more cortical bone planks **{Fig. 7 item 711B}**.

93. The composite bone graft of claim 92, said first cortical bone portion comprises a first face comprising a protrusion and said second cortical bone portion comprises a second face comprising a depression complimentary to said first face, such that said first face and said second face interlock **{page 18 line 27-page 19 line 6}** wherein said composite bone graft does not comprise an adhesive.

94. The composite bone graft of claim 93, said one or more biocompatible mechanical connectors comprise a single cortical bone pin **{page 18 line 27-page 19 line 6}**.

95. The composite bone graft of claim 94, said cortical bone pin comprises a locking pin **{page 18 line 27-page 19 line 6}**, said locking pin partially traverses said graft unit and is located approximately parallel or perpendicular to the interface of said first cortical bone portion and said second cortical bone portion **{Fig. 7 items 711A and 711B}**.

96. The composite bone graft of any one of claims 87, 88, 89, 90, or 91, said composite bone graft further comprising a first top surface and a second bottom surface, said first top surface and

said second bottom surface comprising a plurality of protrusions defining a saw-tooth pattern **{Fig. 7 items 711A and 711B; Fig. 1D-E item 120}**.

97. A composite cervical wedge **{page 3 lines 7-8}**, comprising:

a first substantially planer cortical bone portion **{Fig. 7 item 711A}**;

a second substantially planer cortical bone portion provided on said first substantially planer cortical bone portion to form a graft unit **{Fig. 7 item 711B}**, said graft unit having a top textured surface and a bottom textured surface **{Figs. 1D-E item 120; Fig. 7 items 711A and 711B}**;

one or more biocompatible mechanical connectors for holding together said graft unit **{page 18 line 27-page 19 line 6}**, said one or more biocompatible mechanical connectors are provided perpendicular to or parallel to an interface of said first substantially planer cortical bone portion and said second substantially planer cortical bone portion **{Fig. 7 items 711A and 711B}**; and

a through-hole entirely traversing said composite bone graft **{Figs. 1 and 7 item 104}**, said through-hole is disposed substantially perpendicular to interfaces of adjacent bone portions, forming said composite cervical wedge, said composite cervical wedge comprises:

a first width of from about 7 mm-14 mm **{page 6 lines 1-2; Figs. 6A-I; page 18 lines 8-17}**; a second width of from about 7 mm-14 mm **{page 6 lines 1-2; Figs. 6A-I; page 18 lines 8-17}**; a composite anterior height of from about 7 mm-14 mm **{page 5 lines 24-27; Figs. 6A-I; page 18 lines 8-17}**; a composite posterior height of from about 7 mm-14 mm **{page 5 lines 24-27; Figs. 6A-I; page 18 lines 8-17}**; and a diameter of from about 7 mm-14 mm **{page 6 iine 1-**

2; claim 1}, wherein said top textured surface and said bottom textured surface are opposing and are disposed parallel to interfaces of said bone portions **{Fig. 7 items 711A and 711B}**, said top textured surface and said bottom textured surface comprises a plurality of protrusions defining a saw-tooth pattern **{Fig. 7 items 711A and 711B}**.

98. A composite cervical block **{page 3 lines 7-8}**, comprising:

a first substantially planer cortical bone portion **{Fig. 7 item 711A}**;

a second substantially planer cortical bone portion provided on said first substantially planer cortical bone portion to form a graft unit **{Fig. 7 item 711B}**, said graft unit having a top textured surface and a bottom textured surface **{Figs. 1D-E item 120; Fig. 7 items 711A and 711B}**;

one or more biocompatible mechanical connectors for holding together said graft unit **{page 18 line 27-page 19 line 6}**, said one or more biocompatible mechanical connectors are provided perpendicular to or parallel to an interface of said first substantially planer cortical bone portion and said second substantially planer cortical bone portion **{Fig. 7 items 711A and 711B}**; and

a through-hole entirely traversing said composite bone graft **{Figs. 1 and 7 item 104}**, said through-hole is disposed substantially perpendicular to interfaces of adjacent bone portions **{Fig. 7 items 711A and 711B}**, forming said composite cervical wedge, said composite cervical wedge comprises:

a first width of from about 7 mm-14 mm **{page 6 lines 1-2; Figs. 6A-I; page 18 line 27-page 19 line 6}**; a second width of from about 7 mm-14 mm **{page 6 lines 1-2; Figs 6A-I; page**

18 line 27-page 19 line 6}; a composite height of from about 7 mm-14 mm **{page 5 lines 24-27; Figs. 6A-I; page 18 line 27-page 19 line 6}**; and a diameter of from about 7 mm-14 mm **{page 6 lines 1-2; claim 1}**, wherein said top textured surface and said bottom textured surface are opposing and are disposed parallel to interfaces of said bone portions **{Fig. 7 items 711A and 711B}**, said top textured surface and said bottom textured surface comprises a plurality of protrusions defining a saw-tooth pattern **{Figs. 1D-E item 120; Fig. 7 items 711A and 711B}**.

99. The composite bone graft of any one of claims 87-91, 97, or 98, further comprising osteoinductive substances provided in said through-hole **{page 3 lines 4-7; page 24 lines 8-16}**, said osteoinductive substances are selected from the group consisting of demineralized bone and bone marrow cancellous bone **{page 24 lines 12-13}**.

100. The composite bone graft of claim 99, said osteoinductive substances further comprising one or more members selected from the group consisting of bone morphogenic protein and a growth factor **{page 19 lines 12-17 and page 24 lines 8-16}**.

101. The composite bone graft of claim 100, said through-hole has a diameter of from about 2.0 mm to about 8.0 mm **{Figs. 6A and 6D; page 6 lines 1-2}**.

102. The composite bone graft of any one of claims 86-91, 97, or 98, said bone portions comprising allogenic bone **{page 3 lines 4-5}**.

103. The composite bone graft of claim 90, said two or more distinct, adjacent, bone portions comprise one or more members selected from the group consisting of cortical bone and cancellous bone **{page 4 lines 23-24 and page 6 line 28-page 7 line 3}**.

104. The composite bone graft of claim 103, said cortical bone and said cancellous bone, comprising allogenic bone **{page 3 lines 4-5}**.

105. The composite bone graft of claim 90, said composite bone graft further comprising a top surface; a bottom surface; a diameter of from about 7 mm-14 mm **{page 6 lines 1-2; Figs. 6A-I; page 18 line 27-page 19 line 6; claim 1}**; a width of from about 7 mm-14 mm **{page 6 lines 1-2; Figs. 6A-I; page 18 line 27-page 19 line 6}**; an anterior composite height of from about 7 mm-14 mm **{page 5 lines 24-27; Figs. 6A-I; page 18 line 27-page 19 line 6}**; and a posterior composite height of from about 7 mm-14 mm **{page 5 lines 24-27; Figs. 6A-I; page 18 line 27-page 19 line 6}**.

106. The composite bone graft of claim 105, said top surface and said bottom surface comprising a plurality of protrusions defining a saw-tooth pattern **{Figs. 1D-E item 120; Figs. 7 items 711A and 711B}**.

107. The composite bone graft of any one of claims 98 or 106, said plurality of protrusions having a height of about 4 mm **{Figs. 5C-5E; Fig. 6C; page 17 line 10-page 18 line 7}**.

108. The composite bone graft of any one of claims 61, 87, 91, 97, or 98, said first cortical bone portion comprises one or more cortical bone planks **{Fig. 7 item 711A; page 18 line 18-**

page 19 line 17}, and said second cortical bone portion comprises one or more cortical bone planks **{Fig. 7 item 711B; page 18 line 20-page 19 line 17}**.

109. The composite bone graft of any one of claims 63, 88, 89, or 90, each of said cortical bone portions comprises one or more cortical bone planks **{Fig. 7 items 711A and 711B; page 18 line 20-page 19 line 17}**.

110. The composite bone graft of claim 96, said plurality of protrusions having a height of about 4 mm **{Figs. 5C-5E; Fig. 6C; page 17 line 10-page 18 line 7}**.

VIII. 37 CFR 1.608

37 CFR 1.608 is irrelevant if applicants are accorded the benefit the 27 August 1997 filing date of serial No. 08/920,630 or the 25 August 1998 filing date of serial No. 09/701,933. The filing dates of both of those applications precede the 03 August 1999 filing date of application serial No. 09/368,263 that matured into the Anderson et al. patent. The filing dates of both of those applications also precede the filing dates of the earlier applications cited in column 1 paragraph 1 of the Anderson et al. patent.

IX. SUBMISSION OF PROPOSED FORM PTO-850

Submitted herewith for the convenience of the examiner is a proposed form PTO-850.

Respectfully submitted,

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UNITED STATES PATENT AND TRADEMARK OFFICE

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/905,683	07/16/2001	Jamie M. Grooms	197319US/222962US	4376

22850 7590 08/06/2003

OBLON, SPIVAK, MCCLELLAND, MAIER & NEUSTADT, P.C.
1940 DUKE STREET
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EXAMINER	
SNOW, BRUCE EDWARD	
ART UNIT	**PAPER NUMBER**
3738	10

DATE MAILED: 08/06/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	**Application No.**	**Applicant(s)**	
	09/905,683	BROOMS ET AL.	
	Examiner	**Art Unit**	
	Bruce E Snow	3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 59-110 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 59-110 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Election/Restrictions

This application contains claims directed to the following patentably distinct species of the claimed invention:

Species 1 – figure 1

Species 2 – figure 6

Species 3 – figure 7

Species 4 – figure 8

Species 5 – figure 9

Species 6 – figure 11

Species 7 – figure 12

Species 8 – figure 13

Species 9 – figure 14

Species 10 – figure 15

Species 11 – figure 16

Species 12 – figure 17.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, none are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added.

An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bruce E Snow whose telephone number is (703) 308-3255. The examiner can normally be reached on Mon-Thurs.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on (703)308-2111. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3590 for regular communications and (703) 305-3590 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.

bes
August 4, 2003

BRUCE SNOW
PRIMARY EXAMINER

ATTORNEY DOCKET NO. TB 104IA CA/ 1915/13971US04

IN THE UNITED STATES
PATENT AND TRADEMARK OFFICE

Applicants: **Grooms, James, *et al.***	)	**CERTIFICATE OF MAILING**
U.S. Serial No.: 09/905,683	)	**I hereby certify that this paper (and all papers referred to herein) is being deposited with the United States Postal Service as first class mail, postage prepaid, in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on:**
Filed: July 13, 2001	)	
For: "CORTICAL BONE CERVICAL SMITH-ROBINSON FUSION IMPLANT"	)	**September 11, 2003**
Group Art Unit: 3738	)	**Donald J. Pochopien** **Registration No. 32,167** **Attorney for Applicants**
Examiner: Bruce Edward Snow	)	

PRELIMINARY AMENDMENT AND
RESPONSE TO A RESTRICTION UNDER 35 U.S.C. § 121

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

In response to the Notice of Restriction of invention under 35 U.S.C. § 121, dated 07/06/03, for which a Response is due 09/06/03, now extended 1 month to 10/06/03, the Applicants hereby elect to prosecute the invention of Species 3 (Figure 7), with traverse. The Applicants respectfully submit that the implant of alleged Species 5 (Figure 9), is merely the implant of Species 3 (Figure 7) with a bone plug in the center hole of the implant. Thus, any claim directed to the implant of Species 3 (Figure 7) that used the word "comprising" would inherently read on the implant of Species 5 (Figure 9). For these reasons, Species 3 and Species 5 are clearly a single invention and should be combined for examination.

In addition, the Applicants respectfully submit that Species 7, 9 and 11 differ from one another in size only. As a result, Species 7, 9 and 11 should be grouped together as a single species. Like the relationship between Species 5, which is merely the implant of Species 3 with a plug in the center hole, Species 8, 10 and 12, are the implants of Species 7, 9 and 11, respectively, with a plug in the center hole. Thus, any generic claim to the implant of Species 7 that did not mention size and that used the open-ended term "comprising", would read on the implants of Species 8-12 as well. For these reasons, the implants of Species 7-12 should be combined.

The Applicants respectfully submit that the broad invention made by the Applicants is the concept of making a shaped implant out of several smaller components of cortical bone, alone or in combination with cancellous bone, that are assembled to make the larger shaped implant, wherein the larger pieces are held together without glue but by a plug or one or more bone pins. With that concept in mind, the Applicants respectfully submit that Species 3, 5 and 7-12 are a part of the single inventive concept and should be considered together as a single invention.

Identification of claims associated with species:

Species 3:	Claims 1-16, 38-49, 50-53.
Species 3 and 5:	Claims 1-16, 17-30, 38-49, 50-53, 54-58.
Species 3, 5, 7-12:	Claims 1-16, 17-30, 38-49, 50-53, 54-58.

Amendment to the Specification:

In the Title:

Please delete the title of the specification and substitute therefor the following:

Multi-component Cortical bone ~~cervical Smith-Robinson fusion~~ assembled implant

Please delete the paragraph at page 1, lines 9-11, claiming priority, and substitute in its place the following paragraph:

This application is a continuation of ~~currently pending~~ U.S. Pat. Application No. 09/701,933, filed August 20, 2001, now pending, which is a 371 of PCT/US98/17769, filed August 28, 1998, which is a continuation-in-part of ~~currently pending~~ U.S. Pat. Application No. 08/920,630, filed August 30, 1997, now abandoned, to which the Applicants claim the benefit of priority ~~under 35 U.S.C. § 120~~.

REMARKS

The amendment to the specification does not add new matter. Rather, it updates the status of the claimed priority applications and merely reflects that the claimed priority application, USSN 09/701,933, is the National Phase (371) filing of PCT/US98/17769, which in turn was filed "August 28, 1998" which date is recited in the specification. Moreover, USSN 09/701,933 utilizes the same specification and the same file as PCT/US98/17769. Finally, the Official Filing receipt for the claimed priority application USSN 09/701,933 shows that it is a 371 of PCT/US98/17769. [See Exhibit A hereto.] For all these reasons, the amendment to the specification does not add new matter.

Respectfully submitted,

McANDREWS, HELD & MALLOY, LTD.

By:

Donald J. Pochopien, Ph.D.
Registration No. 32,167
Attorney for Applicants
500 West Madison Street
Suite 3400
Chicago, Illinois 60661
(312) 775-8133

Dated: September 11, 2003

J:\open\DJP\Regeneration Technologies\13971US04\13971US04 Amdt and Response to Restrict.doc

Response to Amendment

The reply filed on 9/15/03 is not fully responsive to the prior Office Action because of the following omission(s) or matter(s): Note that claims 1-58 have been cancelled, claims 59-110 are pending. See 37 CFR 1.111. Since the above-mentioned reply appears to be *bona fide*, applicant is given **ONE (1) MONTH or THIRTY (30) DAYS** from the mailing date of this notice, whichever is longer, within which to supply the omission or correction in order to avoid abandonment. EXTENSIONS OF THIS TIME PERIOD MAY BE GRANTED UNDER 37 CFR 1.136(a).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bruce E Snow whose telephone number is (703) 308-3255. The examiner can normally be reached on Mon-Thurs.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on (703)308-2111. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3590 for regular communications and (703) 305-3590 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.

BRUCE SNOW
PRIMARY EXAMINER

bes
October 7, 2003

Response to Amendment

The reply filed on 9/15/03 is not fully responsive to the prior Office Action because of the following omission(s) or matter(s): Note that claims 1-58 have been cancelled, claims 59-110 are pending. See 37 CFR 1.111. Since the above-mentioned reply appears to be *bona fide*, applicant is given **ONE (1) MONTH or THIRTY (30) DAYS** from the mailing date of this notice, whichever is longer, within which to supply the omission or correction in order to avoid abandonment. EXTENSIONS OF THIS TIME PERIOD MAY BE GRANTED UNDER 37 CFR 1.136(a).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bruce E Snow whose telephone number is (703) 308-3255. The examiner can normally be reached on Mon-Thurs.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on (703)308-2111. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3590 for regular communications and (703) 305-3590 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.

bes
September 25, 2003

BRUCE SNOW
PRIMARY EXAMINER

ATTORNEY DOCKET NO. TB 104IA CA/ 1915/13971US04

IN THE UNITED STATES
PATENT AND TRADEMARK OFFICE

Applicants:
Grooms, James, *et al.*

U.S. Serial No.: 09/905,683

Filed: July 13, 2001

For: "MULTI-COMPONENT CORTICAL BONE ASSEMBLED IMPLANT" (AS AMENDED)

Group Art Unit: 3738

Examiner: Bruce Edward Snow

CERTIFICATE OF MAILING

I hereby certify that this paper (and all papers referred to herein) is being deposited with the United States Postal Service as first class mail, postage prepaid, in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on:

February 16, 2004

Donald J. Pochopien
Registration No. 32,167
Attorney for Applicants

SECOND PRELIMINARY AMENDMENT AND RESPONSE TO A NOTICE OF A NON-COMPLIANT RESPONSE

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

In response to the Notice of A Non-compliant response dated 10/08/03, for which a Response was due 11/08/03, now extended four (4) months to 03/08/04, the Applicants hereby request the entry of the amendment to the claims, and further respond to the restriction requirement of 08/06/03.

Applicants elect to prosecute the invention of Species 3 (Figure 7), with traverse. The Applicants respectfully submit that the implant of alleged Species 5 (Figure 9), is merely the implant of Species 3 (Figure 7) with a bone plug in the center hole of the implant. Thus, any claim directed to the implant of Species 3 (Figure 7) that used the word "comprising" would inherently read on the implant of Species 5 (Figure 9). For these

reasons, Species 3 and Species 5 are clearly a single invention and should be combined for examination.

Identification of claims associated with species:

Species 3:	Claims 111-128
Species 3 and 5:	Claims 111, 123, 124, 126 and 128

Amendment to the Claims:

Please substitute the following claims for any prior set of claims

Claims 1-110 (Cancelled)

111. (New) An assembled bone implant comprising:

a first cortical bone portion;

a second cortical bone portion;

said first cortical bone portion and said second cortical bone portion having one or more through holes sized and positioned for receiving one or more retention pins for connecting said first cortical bone portion to said second cortical bone portion; and

one or more retention pins for connecting said first cortical bone portion to said second cortical bone portion to form said assembled bone implant.

112. (New) The assembled bone implant of claim 111, wherein said first cortical bone portion and said second cortical bone portion each have a D shape.

113. (New) The assembled bone implant of claim 112, wherein said first cortical bone portion is stacked over said second cortical bone portion.

114. (New) The assembled implant of claim 112, wherein said retention pin is selected from the group consisting of cortical bone, a bioabsorbable synthetic polymer and titanium.

115. (New) The assembled implant of claim 114, wherein said retention pin is cortical bone.

116. (New) The assembled implant of claim 111, wherein said first cortical bone

portion is a mirror image of said second cortical bone portion.

117. (New) The assembled implant of claim 112, wherein the graft has a beveled edge of defined radius.

118. (New) The assembled implant of claim 111, wherein said first cortical bone portion and said second cortical bone portion are in a stacked position relative to one another.

119. (New) The assembled implant of claim 116, wherein said first cortical bone portion and said second cortical bone portion are in a side-by-side position.

120. (New) The assembled implant of claim 112, wherein said first cortical bone portion and said second cortical bone portion are allograft bone.

121. (New) The assembled implant of claim 112, sized and shaped in the form of a cervical implant.

122. (New) The assembled implant of claim 112, having a height between 7 and 14 mm.

123. (New) The assembled implant of claim 111, wherein said one or more retention pins comprise a cancellous bone portion.

124. (New) The assembled implant of claim 123, wherein said cancellous bone portion is treated with a bone morphogenetic protein (BMP).

125. (New) The assembled implant of claim 112, wherein said implant has two opposing surfaces that are inscribed with teeth.

126. (New) A D-shaped assembled bone implant for implantation into a patient comprising:

a first cortical bone portion having a D shape; and

a second cortical bone portion having a D-shape;

said first cortical bone portion and said second cortical bone portion being superimposed to form D-shaped implant having the combined thickness of said first cortical bone portion and said second cortical bone portion, said D-shaped implant having a through-hole sized and positioned for receiving a retention pin for retaining said first cortical bone portion to said second cortical bone portion in stacked formation.

127. (New) The assembled implant of claim 126, wherein said retention pin is a cortical bone pin.

128. (New) The assembled implant of claim 126, wherein said retention pin is a cancellous bone portion is treated with a bone morphogenetic protein.

REMARKS

The amendment canceling the claims was necessary because when the file was transferred to the present attorneys, it did not contain any preliminary amendment, canceling claims 1-58 and adding claims 59-110. The present attorneys first knowledge of these claims came after a notice from the Patent Office dated 10/08/03, advising of a non-compliant response. The undersigned attorney performed an on-line search of the status of the application and discovered the preliminary amendment. The undersigned attorney determined that the assignee did not have a copy of the amendment in their files. The undersigned attorney left a voice mail message with Examiner Snow on 02/06/03, requesting a facsimile copy of the amendment. However, the Examiner never returned the telephone call or faxed a copy of the claims. Accordingly, the Applicants submit this amendment, adding claims 111-128 which are directed to Species 3-- the embodiment of Fig. 7.

Support for claims 111-128 is found throughout the specification. In particular, claims 111 and 126, which are directed to an assembled bone implant, comprising two portions of cortical bone, having a through hole in the cortical bone and being held together with a bone pin is found throughout the specification, including at page 5, lines 11-16; page 16, lines 13-30; Figs. 7A - 7B, page 17, lines 10-22; and Figs. 8A - 8B.

Claim 112, which is directed to the assembled bone implant of claim 111, wherein said first cortical bone portion and said second cortical bone portion each have a "D shape," is supported throughout the specification, including Fig. 7, showing the elected implant of Fig. 7 having the shape of the capital letter "D."

Claim 113, which is directed to the assembled bone implant of claim 112, wherein said first cortical bone portion is "stacked" over said second cortical bone portion, is supported throughout the specification, including at page 16, lines 13-15 ("In Figure 7, there is shown a further aspect of this invention in which an implant, either machined as described above, or prior to said machining, is further machined so as to allow **stacking** thereof . . . ."); emphasis added in bold.

Claim 114, which is directed to the "assembled bone implant of claim 112, wherein said retention pin is selected from the group consisting of cortical bone, a bioabsorbable synthetic polymer and titanium," is supported throughout the specification, including at page 5, lines 15-16 ("appropriate retention pins made from any desirable material, including cortical bone, bioabsorbable synthetic polymer, titanium and other metallic retention pins").

Claim 115, which is directed to the assembled bone implant of claim 114, 'wherein said retention pin is cortical bone," is supported throughout the specification, including at page 5, line 15 ("appropriate **retention pins** made from any desirable material, including **cortical bone**. . ."); and at page 16, line 23 ("**Pins**, composed of **cortical bone**. . . ."); emphasis added in bold.

Claim 116, which is directed to the assembled bone implant of claim 111, wherein said first cortical bone portion is a "mirror image" of said second cortical bone portion, is supported throughout the specification, including at page 3, lines 8-9 ("Figure 8 provides several views of an implant of this invention formed by juxtaposition of **mirror half images** of the implant. . . ."); emphasis added in bold.

Claim 117 which is directed to the assembled bone implant of claim 112, wherein the graft has "a beveled edge of defined radius," is supported throughout the specification, including at page 9, lines 8-9 ("a **beveled edge of defined radius** is preferably machined into three faces of the implant . . . .").

Claim 118, which is directed to the assembled bone implant of claim 111, wherein said first cortical bone portion and said second cortical bone portion are in a "stacked position" relative to one another, is supported throughout the specification, including at page 16, lines 13-15 ("In Figure 7, there is shown a further aspect of this invention in which an implant, either machined as described above, or prior to said machining, is further machined so as to allow **stacking** thereof . . . ."); emphasis added in bold.

Claim 119, which is directed to the assembled bone implant of claim 116, wherein said first cortical bone portion and said second cortical bone portion are in a side-by-side position, is supported throughout the specification, including at page 17, lines 11-16 ("In

figure 8A, there is shown an implant 800 composed of two **side-by-side** halves, 801A and 801B. The two halves are brought into juxtaposition to form a unitary implant. The two halves may be implanted in juxtaposition, or **holes may be formed in each half,** and the halves maintained in contact by forcing **pins through** the **holes**, in a fashion described above for maintaining stacked implants . . . ."); emphasis added in bold.

Claim 120, which is directed to the assembled bone implant of claim 112, wherein said first cortical bone portion and said second cortical bone portion are allograft bone, is supported throughout the specification, including at page 2, lines 20-21 ("the implant is derived from allograft or autograft cortical bone sources"); emphasis added in bold.

Claim 121, which is directed to the assembled bone implant of claim 112, sized and shaped in the form of a "cervical implant," is supported throughout the specification, including at page 2, lines 23-25 ("The **implant** is inserted into the space between adjacent **cervical** vertebrae to provide support and induce fusion of the adjacent vertebrae"); emphasis added in bold.)

Claim 122, which is directed to the assembled bone implant of claim 112, having a height between 7 and 14 mm, is supported throughout the specification, including at page 5, line 2 ("final implant heights from about 7 to about 14 mm may be produced").

Claim 123, which is directed to the assembled bone implant of claim 111, wherein said one or more retention pins comprise a "cancellous bone" portion, is supported throughout the specification, including at Fig. 9, the description of Fig. 9 at page 3, lines 13-15 ("bringing more than one implant into contact with each other and having a **cancellous** plug . . . located in the central canal of each stacked implant, thereby **acting as a retention pin**") and at page 17, lines 4-9 ("By press-fitting the two implants together using an appropriately shaped **cancellous** plug 905 . . . optionally treated with bone morphogenetic protein and the like, the two implants 901 and 902 are retained in registered juxtaposition to form the implant 900.")

Claim 124, which is directed to the assembled bone implant of claim 123, wherein the "cancellous bone portion is treated with a bone morphogenetic protein" (BMP), is supported throughout the specification, including at page 17, lines 4-9 ("By press-fitting

the two implants together using an appropriately shaped cancellous plug **905** . . . optionally treated with **bone morphogenetic protein** and the like, the two implants **901** and **902** are retained in registered juxtaposition to form the implant **900**"); emphasis added in bold.

Claim 125, which is directed to the assembled bone implant of claim 112, wherein said implant has two opposing surfaces that are "inscribed with teeth", is supported throughout the specification, including at Fig. 7B; the description of Fig. 7B at page 16, lines 28-31, ("In figure 7B, there is shown the juxtaposition of two implants 700A and 700B, with the drilled holes 701-704 in register to receive pins for maintaining the implants in register. In this view, the adjacent surfaces 710A and 710B have not been **inscribed with teeth**, while the [opposing] **surfaces** 711A and 711B **have been so inscribed.**"); at page 18, line 6 ("the side faces are machined to display a rough, ridged or grooved surface"); at page 18, lines 10-13 ("an angle 820 for each **tooth** of between 30 and 40 degrees . . . a distance between **tooth** crests of 821 of about 1-2 mm . . . a **tooth** height 823 of between about 0.1 to about 1 mm . . .);" and at page 9, lines 1-3 ("Alternatively, the implant is passed several times over a rigid surface which cuts the desired **tooth profile** into the **upper**, **lower** or **both surfaces** of the implant. Preferably, the thus formed teeth angle toward the anterior (convexly curved) face of the implant to prevent backing out of the implant once it is inserted into an appropriately shaped cavity . . . ."); emphasis added in bold. xxx

Claim 126, which is directed to a D-shaped implant, is supported by the same disclosures that support claim 111 (assembled implant) and claim 112 (D-shaped). Claim 127, which is directed to the implant of claim 126, wherein said "retention pin is a cortical bone pin," is supported throughout the specification, including at page 5, line 15 ("appropriate **retention pins** made from any desirable material, including **cortical bone**. . ."); and at page 16, line 23 ("**Pins**, composed of **cortical bone**. . . ."); emphasis added in bold.

Claim 128, which is directed to the assembled implant of claim 126, wherein said retention pin is a "cancellous bone portion is treated with a bone morphogenetic protein," is supported throughout the specification, including at Fig. 9, the description of Fig. 9 at page 3, lines 13-15 ("bringing more than one implant into contact with each other and having a **cancellous** plug . . . located in the central canal of each stacked implant, thereby

acting as a retention pin") and at page 17, lines 4-9 ("By press-fitting the two implants together using an appropriately shaped **cancellous** plug 905 . . . optionally treated with bone morphogenetic protein and the like, the two implants 901 and 902 are retained in registered juxtaposition to form the implant 900."); and at page 17, lines 4-9 ("By press-fitting the two implants together using an appropriately shaped cancellous plug **905** . . . optionally treated with **bone morphogenetic protein** and the like, the two implants **901** and **902** are retained in registered juxtaposition to form the implant **900**"); emphasis added in bold.

For all these reasons, the new claims are fully supported by the disclosures in the specification and do not add new matter. The claims are in condition for allowance. Their allowance is respectfully requested.

Respectfully submitted,

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Dated: February 16, 2004

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/905,683	07/16/2001	Jamie M. Grooms	197319US/222962US	4376

7590 03/16/2004

EXAMINER
SNOW, BRUCE EDWARD

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500 WEST MADISON STREET
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ART UNIT	PAPER NUMBER
3738	

DATE MAILED: 03/16/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/905,683	Applicant(s) GROOMS ET AL.
	Examiner Bruce E Snow	Art Unit 3738

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on 20 February 2004.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 111-128 is/are pending in the application.

4a) Of the above claim(s) 119 is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 118 and 120-128 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date 11212002, 12032001.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of Species 3 (figures 7) in Paper No. 0202004 is acknowledged. The traversal is on the ground(s) that the species shown in figure 9 should be included with Species 3. This is not found persuasive. It is noted that the two figures show patentable distinct features not inclusive to both.such as elements 701-704 of figures 7 and element 904 in figure 9. All claims 111-118 and 120-128 read on the elected Species; claim 119 is withdrawn.

The requirement is still deemed proper and is therefore made FINAL.

Double Patenting

All claims are provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of all claims of copending Application No. 10/375,540. This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 111-118 and 120-128 are rejected under 35 U.S.C. 103(a) as being unpatentable over Coates et al (5,989,289) in view of Siebels (EP 517030).

Referring to all figures, Coates teaches a D-shaped cortical bone spinal implant (see

column 11, lines 42 et seq.). However, Coates et al fails to teach said implant can comprise a first and second portion capable of being connected by a pin. Siebels also teaches a spinal implant and teaches stacking portions 11 of the implant and connecting said portions with pins 17. It would have been obvious to one having ordinary skill in the art to have utilized the teachings of Siebels to stack and connect individual implant portions with the D-shaped cortical bone implant of Coates wherein multiple portions could be stacked and connected by at least one pin in corresponding through holes to adjustably build the implant to a desired height (thickness) to best fill the disc space as desired by the surgeon.

Regarding at least claims 114, 123, and 127, lacking any criticality in the specification, the use of the claimed materials such as titanium in lieu of those taught by Seibels produce no advantage and is considered an obvious matter of design choice. Additionally, Coates teaches the use of metal devices are foreign bodies which can never be fully incorporated in the fusion mass and produce stress shielding because the stiffness values do not match that of bone (column 2, lines 34 et seq.). Therefore, it would have been obvious to one having ordinary skill in the art to have constructed the pin out of cortical bone or cancellous bone which can be fully incorporated and does not produce stress shielding.

Regarding claim 122, see column 11, lines 62 et seq.

Regarding claims 124 and 128, Coates et al teaches treating the spacer with BMP which would include the pins.

All other claimed limitations are self-evident.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bruce E Snow whose telephone number is (703) 308-3255. The examiner can normally be reached on Mon-Thurs.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on (703)308-2111. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

bes

BRUCE SNOW
PRIMARY EXAMINER

Form PTO-1449 (Rev. 8-83) (modified) U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE **INFORMATION DISCLOSURE CITATION** (Use several sheets if necessary)	ATTY. DOCKET NO. TB-104IA CA 1915/13971US04	SERIAL NO. 09/905,683
	APPLICANT(s): Grooms, James, *et al.*	
	FILING DATE July 13, 2001	GROUP ART UNIT: 3732

U.S. PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NO.	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
[initials]	A1	6,277,149 B1	08/21/01	Boyle, *et al.*			

FOREIGN PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NO.	PUBLICATI ON DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION	
							YES	NO

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

EXAMINER	DATE CONSIDERED:
[signature]	3/15/04

*EXAMINER: Initial citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Please type a pl[redacted]) inside this box →+

PTO/SB/08A (10-96)
Approve[redacted] through 10/31/99. OMB 0651-0031
Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
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Substitute for form 1449A/PTO	Complete if Known	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT	Application Number	09/905,683
	Filing Date	7/16/2001
	First Named Inventor	Grooms *et al.*
	Group Art Unit	Unknown
(use as many sheets as necessary)	Examiner Name	Unknown
Sheet 1 of 2	Attorney Docket Number	TB-104IACA

U.S. PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	U.S. Patent Document Number	Kind Code[2] (if known)	Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		5,306,309		Wagner et al.	04-26-1994	
		5,609,635		Michelson	03-11-1997	
		5,306,307		Senter et al.	04-26-1994	
		4,950,296		McIntyre	08-21-1990	
		6,258,125		Paul et al.	07-10-2001	
		5,522,899		Michelson	06-04-1996	
		5,397,364		Kozak et al.	03-14-1995	

FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Foreign Patent Document Office[3]	Number[4]	Kind Code[5] (if known)	Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T[6]

Examiner Signature		Date Considered	3/11/04

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

[1]Unique citation designation number. [2]See attached Kinds of U.S. Patent Documents. [3]Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). [4]For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [5]Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. [6]Applicant is to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231.

Notice of References Cited	Application/Control No. 09/905,683	Applicant(s)/Patent Under Reexamination GROOMS ET AL.	
	Examiner Bruce E Snow	Art Unit 3738	Page 1 of 1

U.S. PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Name	Classification
	A	US-5,989,289	11-1999	Coates et al.	623/17.16
	B	US-5,571,190	11-1996	Ulrich et al.	623/17.11
	C	US-5,192,327	03-1993	Brantigan, John W.	623/17.11
	D	US-5,728,159	03-1998	Stroever et al.	623/23.5
	E	US-4,349,921	09-1982	Kuntz, J. David	623/17.16
	F	US-5,861,041	01-1999	Tienboon, Prakit	623/17.16
	G	US-			
	H	US-			
	I	US-			
	J	US-			
	K	US-			
	L	US-			
	M	US-			

FOREIGN PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Country	Name	Classification
	N	517030	05-1992	EP	Siebels	
	O					
	P					
	Q					
	R					
	S					
	T					

NON-PATENT DOCUMENTS

*		Include as applicable: Author, Title Date, Publisher, Edition or Volume, Pertinent Pages)
	U	
	V	
	W	
	X	

*A copy of this reference is not being furnished with this Office action. (See MPEP § 707.05(a).)
Dates in MM-YYYY format are publication dates. Classifications may be US or foreign.

(19) Europäisches Patentamt
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(54) Wirbelkörperimplantat.

(57) Als Implantat für Wirbelsäulen wird eine Scheibe (11) vorgeschlagen, die alleine oder zu mehreren gestapelt (11 bis 14) zwischen Wirbelkörper einsetzbar sind. Einzelne Scheiben werden nach Bedarf von einem Strang abgeschnitten, wobei die Scheibendikke dem Einzelfall genau angepaßt werden kann. Diese Implantate eignen sich insbesondere für Halswirbel sowie als Ersatz nach der Entfernung von Bandscheiben. Für die Bildung eines Implantats aus mehreren übereinandergestapelten Scheiben kann ein entsprechendes Sortiment von Scheiben bereitgestellt werden, die sich sowohl im Durchmesser als auch in der Höhe unterscheiden. Für den jeweiligen Anwendungszweck werden demzufolge Scheiben mit entsprechender Dicke ausgesucht und zusammengesetzt, so daß sie insgesamt die erforderliche Höhe des Implantats ergeben. Verschraubungen und insbesondere längere Handhabungen im eingesetzten Zustand des Implantats sind bei dem erfindungsgemäßen Implantat nicht erforderlich.

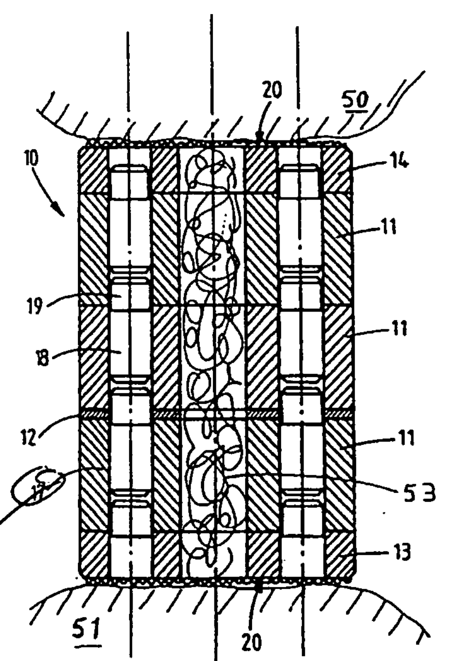

Fig.1

EP 0 517 030 A2

Auch die Scheibenpackungen können als Ringscheiben ausgebildet werden, wobei der Hohlraum zur radialen Verankerung der Ringe mit Knochenmaterial oder -zement ausgefüllt werden kann. Vorteilhaft ist es, wenn der Innenmantel der Ringscheiben unregelmäßig ist oder geometrische Unregelmäßigkeiten aufweist. jede Abweichung von der kreiszylindrischen Form dient zur drehsicheren Verankerung der aufgestapelten Scheiben, wenn der Hohlraum der Ringscheiben mit einem härtenden Material ausgefüllt wird.

Für den sicheren Halt des als Scheibenstapel ausgebildeten Implantats zwischen den angrenzenden Wirbelkörpern werden Endscheiben mit einer rauhen Stirnseite vorgesehen. Die Rauhigkeit kann durch eine strukturierte Oberfläche, herausragende Spitzen, Wellen und dergleichen erzeugt werden.

In jeder Ausführung ist es möglich, die Scheiben zu einer soliden Einheit miteinander zu verkleben, z.B. mit PMMA-Zement, wenn erforderlich oder zweckmäßig.

Die Scheiben werden vorzugsweise aus einem kohlenstoffaserverstärkten Kunststoff (CFK) hergestellt, wobei die Verankerungsmittel je nach Ausgestaltung des Implantats aus demselben oder einem anderen Material bestehen können. Die Herstellung des gesamten Implantats aus CFK hat den Vorteil, daß das Implantat keine Streuung von Strahlen bewirkt, so daß die Wirbelsäule und das angrenzende biologische Gewebe auch nach dem Implantieren eines Wirbelkörperersatzes mit allen bildgebenden Verfahren (CT, MR) untersucht werden kann

Bekannte Wickeltechniken lassen sich zur serienmäßigen Fertigung der Implantat-Elemente anwenden. Die Ringscheiben können beispielsweise mittels einer Flechtmaschine, die zusätzlich mit unidirektionalen Fasern (UD) bestückt ist, hergestellt werden. Mittels eines Stabdornes, der durch das Flechtauge gezogen und mit UD-Fasern und Flechtwerk umlegt wird, wird ein Faserverbundrohr in einem Arbeitsgang hergestellt, von dem dann die Ringscheiben abgeschnitten werden. Der Stabdorn ist vorzugsweise aus dem auch als Trennmittel verwendbaren PTFE (Polytetrafluorethylen). Der Stabdorn kann dabei ein Vieleck als Querschnitt haben oder über die Länge Nuten und/oder Erhebungen aufweisen, wodurch im Faserverbundrohr bzw. in den Ringscheiben die für die drehsichere Verankerung dieerforderliche Innenmantelgeometrie direkt bei deren Herstellung gebildet wird.

Auch Wickelverfahren unter Anwendung von Fasern oder Fasergelegen erlauben fertigungstechnisch einfache und für Serienfertigung geeignete Herstellverfahren. Es können einheitliche Streben für die Einzelscheiben und die Scheibenpackungen konzipiert werden.

Die Erfindung wird anhand von in der Zeichnung schematisch dargestellten Ausführungsbeispielen näher erläutert. Es zeigen:

Figuren 1 und 2
ein erstes Ausführungsbeispiel,
Figuren 3 und 4
ein zweites Ausführungsbeispiel,
Figuren 5 bis 8
je ein weiteres Ausführungsbeispiel.

Der Erfindung liegt der Gedanke zugrunde, daß der Chirurg an Ort und Stelle direkt nach Kenntnis der tatsächlichen Abmessungen den Wirbelkörperersatz zusammenstellt, ohne die Hilfe eines Prothesentechnikers. Dazu wir ein Vorrat von Strängen unterschiedlicher Durchmesser und/oder eines Sortiments von Implantatkomponenten unterschiedlicher Durchmesser und Höhen gehalten, so daß für den jeweiligen Fall entweder eine entsprechende dicke Scheibe aus dem entsprechenden Strang heraugetrennt oder die entsprechende Anzahl von Komponenten mit entsprechenden Abmessungen herausgeholt und zusammengesetzt zu werden braucht, ohne Schraubjustier-oder andere Handgriffe vornehmen zu müssen. Die Auswahl der Scheiben nach ihrer Höhe im letzten Fall kann mittels eines Rechners erfolgen.

Die Grundlage eines zusammengesetzten Implantats besteht im Aufstapeln von vorgefertigten Scheiben, wobei diese Scheiben eine runde, mehreckige oder unregelmäßige Außenkontur haben können. Es können volle Scheiben oder auch Ringscheiben als Komponenten verwendet werden. Es werden Scheibensätze mit unterschiedlichen Durchmessern benötigt, wobei jeder Satz eines Durchmessers mit Scheiben unterschiedlicher Höhe bestückt ist. Steht der Durchmesser des einzusetzenden Implantats fest, so werden in dem entsprechenden Scheibensatz noch die entsprechenden Höhen ausgesucht, so daß nach dem Zusammensetzen der gewählten Scheiben sich die erforderliche Implantathöhe ergibt.

Um das Sortiment bezüglich der Scheibenhöhe möglichst klein zu halten, können beispielsweise wenige hohe Abmessungen vorgesehen werden, die mit niedrigen Scheiben, z.B. millimeterdicken Scheiben, entsprechend ergänzt werden.

In Fig. 1 ist ein Ausführungsbeispiel gezeigt, bei dem ein fertiges Implantat 10 aus drei dickeren Scheiben 11, einer dünnen Scheibe 12 und zwei Endscheiben 13 bzw. 14 zusammengesetzt ist.

Wie in Fig. 2 dargestellt ist, bestehen die Scheiben 11 bis 14 aus runden Ringscheiben mit einer Innenbohrung 15 und jeweils vier regelmäßig auf die Ringscheibe verteilten ~~Bohrungen 16~~. In diese Bohrungen 16 werden Verankerungsstifte 17 eingeführt. Gemäß der Ausführung nach ~~Fig. 1~~ sind die Stifte 17 mit ihrem jeweils einem Ende 18 mit einer Scheibe 11, 13 verbunden, während sie mit dem anderen Ende 19 in die Bohrung einer näch-

pern feststellbar ist, wird mittels dieses Wertes im Rechner die Zusammensetzung der Scheibenhöhen für das Implantat errechnet, herausgesucht und zusammengesetzt oder mittels eines genau einstellbaren Werkzeugs die Scheibe vom Strang abgetrennt. Die angrenzenden Wirbelkörper werden etwas auseinandergezogen und das im Baukastensystem zusammengesetzte Implantat bzw. die Scheibe zwischengelegt. Außer dem Plazieren des Implantats sind keine weiteren Handgriffe bezüglich des Implantats notwendig. Außer der Implantathöhe variiert auch der Durchmesser des Implantats. Das Scheiben- und/oder Strangsortiment ist daher auch nach Querschnitten zu bestücken.

In Fig. 8 ist schließlich ein hohler Strang 50 unregelmäßiger Konfiguration gezeigt, der aus 1 bis 20 Flechtwerken 51 gebildet ist. Ein nicht gezeigter Dorn wird entsprechend oft durch das Ringfadenauge einer Flechtmaschine gezogen und dabei mit entsprechend vielen Flechtwerken und Matrixmaterial überzogen. Mit Trennscheiben werden an Trennlinien 52 die Scheiben 53 für ein Implantat oder Implantatelement herausgeschnitten.

Patentansprüche

1. Implantat für die Wirbelsäule, bestehend aus mindestens einem steifen Element, dadurch gekennzeichnet, daß das Implantat aus mindestens einer Scheibe (11 bis 14, 21, 35, 45, 53) besteht, die direkt zwischen zwei angrenzenden Wirbelkörpern zwischenlegbar ist und je nach Wirbellage parallele oder zueinander im Winkel stehende Auflageflächen hat.

2. Implantat nach Anspruch 1, dadurch gekennzeichnet, daß die Scheibe als Ringscheibe (35, 45, 53) mit regelmäßigem oder unregelmäßigem Umfang ausgebildet ist, und daß der Innenumfang der Scheibe einen vieleckigen oder unregelmäßigen Querschnitt hat.

3. Implantat nach Anspruch 1 oder 2, dadurch gekennzeichnet, daß die Auflageflächen der Scheibe (14, 35, 53) Rauhigkeiten, Porenwelligkeiten oder andere Unebenheiten aufweisen.

4. Implantat nach Anspruch 1, dadurch gekennzeichnet, daß die Auflageflächen der Scheiben (14, 35, 53) herausragende Spitzen (20) aufweisen.

5. Implantat nach einem der vorhergehenden Ansprüche, dadurch gekennzeichnet, daß die Scheibe (45) Kanäle (46) aufweist, in die Knochenzement oder Knochenmaterial einbringbar ist.

6. Implantat nach einem der vorhergehenden Ansprüche, dadurch gekennzeichnet, daß die Scheibe (11 bis 14, 2135, 45, 53) aus faserverstärktem Kunststoff besteht und im Wickelverfahren oder ausaufgerollten Fasermatten hergestellt ist.

7. Implantat nach einem der vorhergehenden Ansprüche, dadurch gekennzeichnet, daß die Scheibe (53) aus einem Strang (32, 33 bzw. 50) geschnitten ist.

8. Implantat nach Anspruch 7, dadurch gekennzeichnet, daß der Strang (32, 33 bzw. 50) aus unidirektionalen Fasern (32) und/oder Flechtlagen (33, 51) besteht.

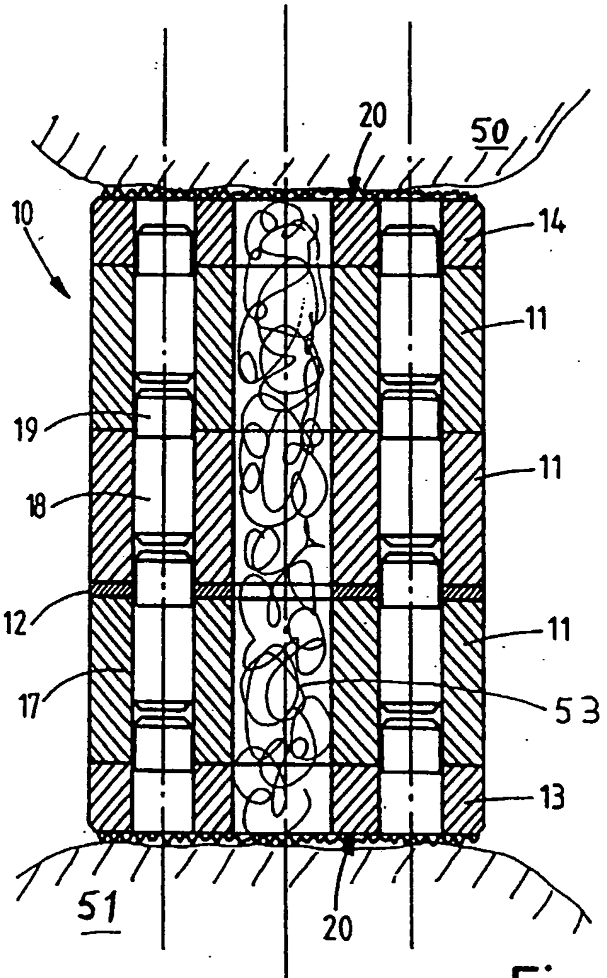

Fig.1

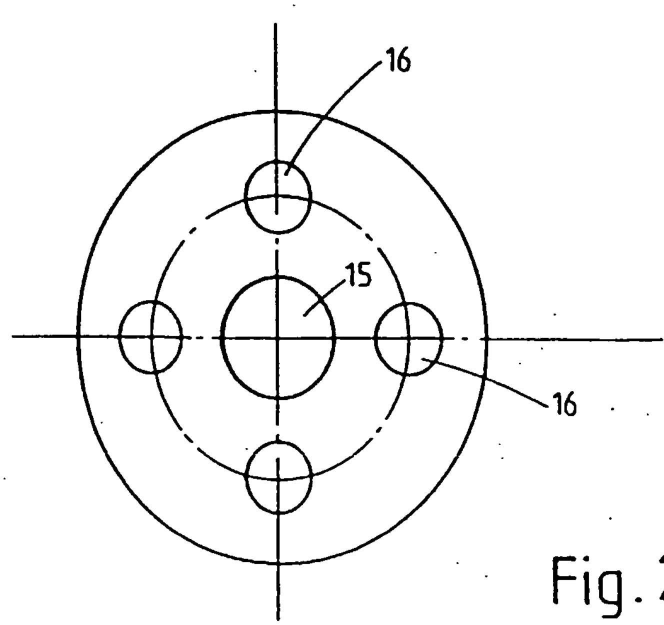

Fig. 2

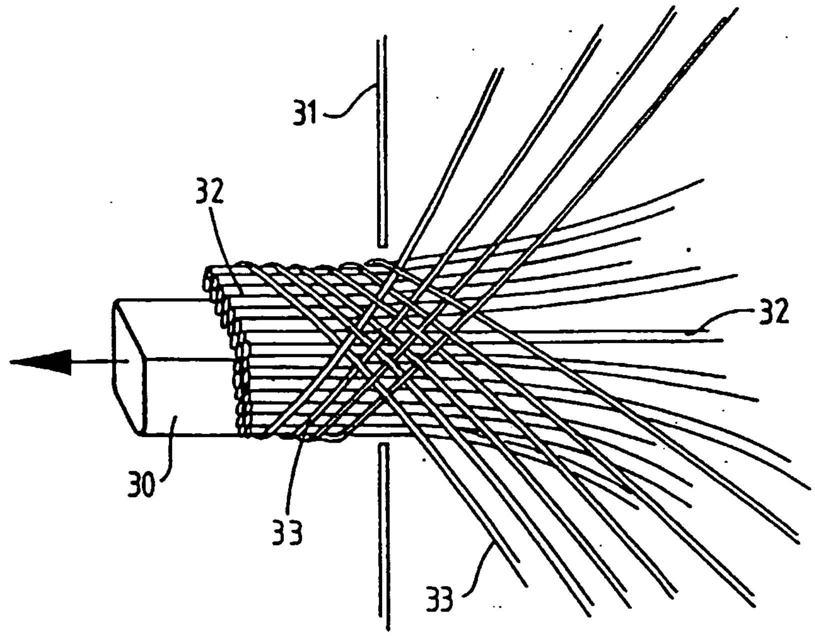

Fig. 5

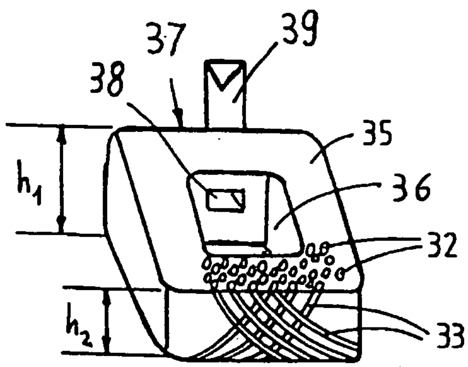

Fig. 6

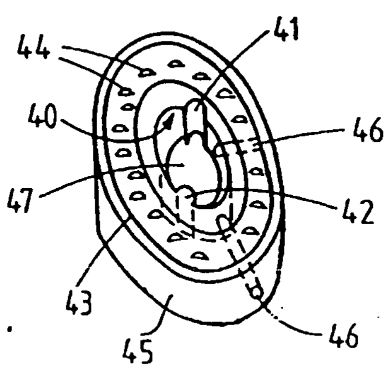

Fig. 7

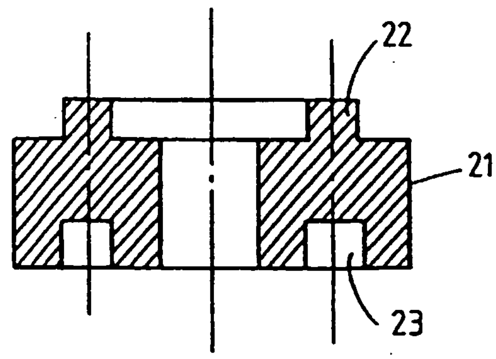

Fig.3

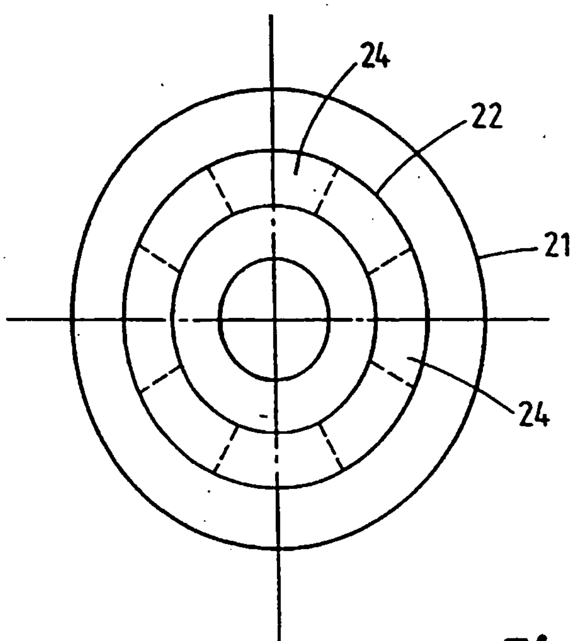

Fig.4

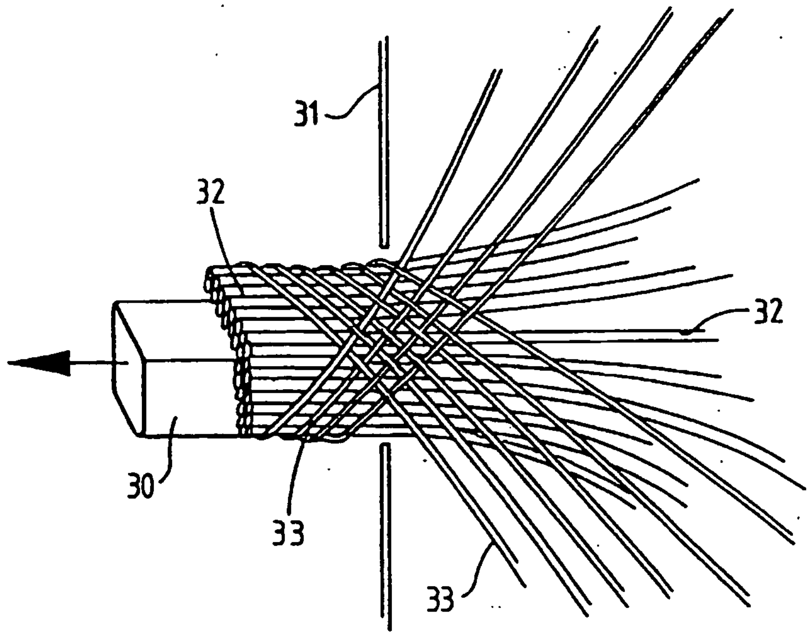

Fig. 5

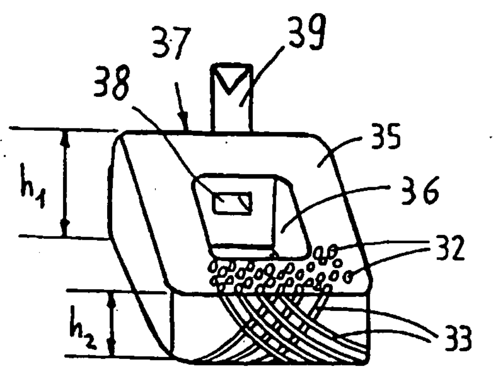

Fig. 6

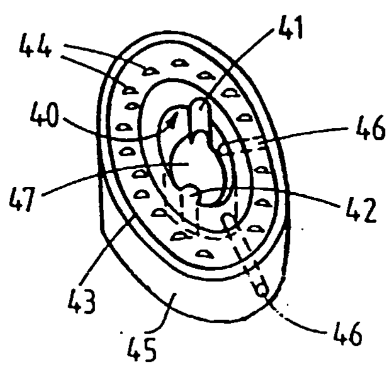

Fig. 7

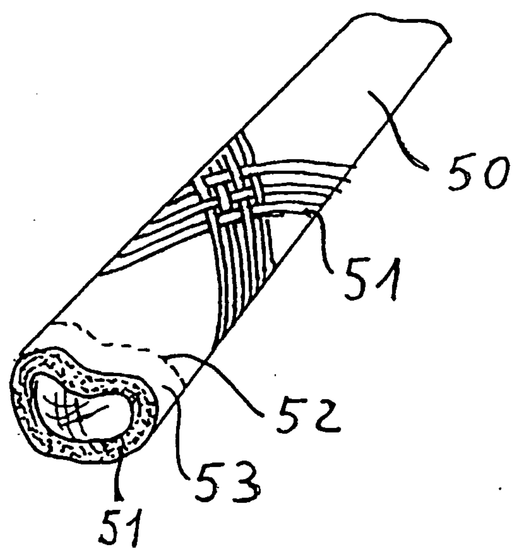

Fig. 8

ATTORNEY DOCKET NO. TB 104IA CA/ 1915/13971US04

IN THE UNITED STATES
PATENT AND TRADEMARK OFFICE

Applicants:
Grooms, James, *et al.*

U.S. Serial No.: 09/905,683

Filed: July 13, 2001

For: "MULTI-COMPONENT CORTICAL BONE ASSEMBLED IMPLANT" (AS AMENDED)

Group Art Unit: 3738

Examiner: Bruce Edward Snow

CERTIFICATE OF MAILING

I hereby certify that this paper (and all papers referred to herein) is being deposited with the United States Postal Service as first class mail, postage prepaid, in an envelope addressed to: Mail Stop Amendment, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on:

September 16, 2004

Donald J. Pochopien
Registration No. 32,167
Attorney for Applicants

AMENDMENT AND RESPONSE UNDER 37 C.F.R. 1.111

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

In response to the Official Action of 03/16/04, for which a Response was due 06/18/04, now extended three (3) months to 09/16/04, the Applicants hereby request the entry of the following amendments before consideration of the arguments on the merits.

Amendments to the specification:	pages 2-8
Amendments to the claims:	pages 9-11
Remarks:	pages 12-22

Amendment to the Specification:

Please delete the paragraphs beginning at page 2, line 28 and ending at page 3, line 22 and substitute therefor the following paragraphs:

~~FIG. 1 provides~~ FIGS. 1A-1D provide several views of ~~the fusion~~ a substantially "D"-shaped cortical bone implant of this invention. FIG. 1E shows the detail of the inscribed feature of FIG. 1D.

~~FIG. 2 provides~~ FIGS. 2A and 2B provide side and end-on views~~,~~ respectively of the core cutter and drill assembly. FIGS. 2C and 2D provide views ~~and~~ of the bone plug formed by cutting into the diaphysis of a long bone when such a core cutter and drill assembly is used.

FIG. ~~3~~ 3A provides a view of broach as used according to this invention. ~~and~~ FIG. 3B provides an end-on view of an asymmetric canal in a cancellous bone plug formed by use of such a broach.

~~FIG. 4 provides~~ FIGS. 4A–4E provide several views of an apparatus for machining a profile on the exterior surface of ~~the~~ an implant of this invention.

FIG. ~~5~~ 5A provides a top view of an apparatus for inscribing retention teeth in the upper surface, lower surface or both upper and lower surfaces of the implant. FIG. 5B is a side-view of a implant mounting device having a "D"-shaped cavity. FIGS. 5C-5E provide views of an alternate apparatus and method for fashioning the retention teeth in an implant.

~~FIG. 6 provides~~ FIGS. 6A-6C, 6D-6F and 6G-6I, respectively, provide several views and dimensions for three specific embodiments of ~~the~~ an implant of this invention.

FIG. 7A is a top view of an implant into which four holes have been drilled. FIG. ~~7~~ 7B

provides a side view of a stacked embodiment of ~~the implant~~ two implants of FIG. 7A of this invention shown in juxtaposition.

FIG. ~~8~~ 8A provides ~~several views~~ a view of an implant of this invention formed by juxtaposition of mirror image halves of the implant~~;~~. FIGS. 8B and 8C shows the implants of the invention in bone stock. FIGS. 8D-8G show several views of ~~as well as~~ an embodiment useful for posterior lumbar intervertebral fusion procedures (PLIFs).

FIG. 9 provides a view of a stacked embodiment of the implant of this invention wherein the stacked constituents thereof are retained in registered relationship by press-fitting or otherwise bringing more than one implant into contact with each other and having a cancellous plug or other biocompatible material located in the central canal of each stacked implant, thereby acting as a retention pin.

~~FIG. 10 shows~~ FIGS. 10A and 10B show an alternate method for producing bone stock for making the implant of this invention of essentially unlimited height from the anterior margin of the tibia (FIG. 10B) or the linea aspera of the femur (FIG. 10A). FIG. 10C shows an end of a section of long bone.

FIG. 11 shows dimensions and further processing of the ~~implant of this invention produced according to the alternate method of~~ bone of FIG. ~~10~~ 10C.

~~FIGS. 12-17 show final profiles for implants~~ FIGS.12A-12D show several views of an implant produced according to the alternate method of FIGS. 10 and 11. FIG. 12A is a top view and the outer dotted profile provides a means for comparing the external profile of the implant with the implant of FIG. 6. FIG. 12B is a side view; FIG. 12C is a detail view of the grooves which angle toward the posterior of the implant; and FIG. 12D is a sectional view through line A shown in FIG. 12A. xxx

FIGS. 13A-13D correspond to the views of the implant of FIGS. 12A-12D, further containing a cancellous plug shown as a top view in FIG. 13E and as a side view in FIG. 13E.

FIGS. 14A-14D are views of an implant that correspond to the views in FIGS. 12A-12D but that has different dimensions as per Table I.

FIGS. 15A-15D correspond to the views of the implant of FIGS. 14A-14D, further containing a cancellous plug shown as a top view in FIG. 15E and as a side view in FIG. 15E.

FIGS. 16A-16D are views of an implant that correspond to the views in FIGS. 12A-12D but that has different dimensions as per Table I.

FIGS. 17A-17D correspond to the views of the implant of FIGS. 16A-16D, further containing a cancellous plug shown as a top view in FIG. 16E and as a side view in FIG. 16E.

Please delete the paragraph beginning at page 14, line 25 of the specification, and substitute therefor the following paragraph:

In ~~figure, figure~~ FIG. 5A, there is provided a top view of one side of one embodiment of blades 502 for use in a broach assembly 500 for inscribing teeth into the top 110, bottom 111 or both surfaces of the implant. In outline, there is shown a lock-down handle 501 for clamping the assembly of blades 502 to a base 503. By bringing a mirror image jaw into register with the depicted broach, a space is formed between the opposing teeth 502 at a

distance sufficient to accommodate passage of the implant therebetween, provided that the teeth abrade recesses into the top and bottom surfaces of the implant 100. To ensure proper engagement of the blades 502 and the implant 100, there is provided a non-cutting surface 506 for contacting the implant 100 as it is introduced into the broach assembly 500. The non-cutting surface 506 acts as a type of micrometer, forcing the cutting surfaces of the teeth 502 sufficiently apart to properly engage the implant as it passes through the broach assembly 500. In ~~figure~~ FIG. 5B, there is provided a side view of an implant mounting device 504 having a "D"-shaped cavity 505 into which a "D"-shaped implant may be fitted for passage through the opposing jaws of the broaching jaw apparatus 500. The resultant implant has the profile shown in ~~figures~~ FIGS. 1C-1E.

Please delete the paragraph beginning at page 17, line 24 of the specification, and substitute therefor the following paragraph:

In addition to use for cervical Smith-Robinson type fusion, implants comprising each element, 801A or 801B alone, modifications and variations thereof, optionally in combination with another vertebral fusion implant, may be implanted, for example, to assist in induction of posterior lumbar intervertebral fusion (PLIF). In such a case, a device 810, such as that shown in ~~figures~~ FIGS. 8D-8G is machined from bone stock as shown in ~~figures~~ FIGS. 8B, 8C or another appropriate bone stock, and is inserted, according to methods known in the art for insertion of PLIF implants. Preferably, the device as used for PLIF applications has the following dimensions similar to the following, see ~~side~~ top view ~~figure~~ FIG. 8D: a width 811 of approximately 7 to 12 mm, and preferably about 9.4 to about 10 mm; a top dimension 812 of about 4 to 5 mm; a bottom dimension 813 of about 4-6 mm and preferably about 5 mm; a flat surface of 814 of about 4-7 mm, and preferably about 5.5 mm; a width 815 of about 5-7 mm and preferably about 5 mm; a curvature that defines an angle 816 of between about 60 and 75 degrees, and preferably about 67 degrees.

See ~~figure~~ FIG. 8E, rear view: a length L of about 20 to 26 mm; a height H of between about 7.5 and 14.5 mm; preferably, heights of about 8, 10, 12, and 14 mm are produced with lengths of about 20 and 26 mm; desirably, the side faces 817 are machined to display a rough, ridged or grooved surface so that when the anterior end 818 of the PLIF implant is properly seated in place, ridges directed to the posterior end 819 of the PLIF implant prevent backing out of the implant. A detail of one embodiment of such a ridged surface is shown in ~~figure~~ FIG. 8F, wherein the following dimensions are preferred: an angle 820 for each tooth of between about 30 and 40 degrees, preferably about 35 degrees; a distance between tooth crests 821 of about 1-2 mm, preferably about 1.5 mm; a tooth crest width 822 of about 0.1 to about 0.2 mm, preferably about 0.125 mm; and a tooth height 823 of between about 0.1 to about 1 mm and preferably about 0.5 mm; returning to ~~figure~~ FIG. 8E, the implant preferably has an anterior end width 824 of about 7-13 mm, preferably about 9-13 mm, with a taper angle 825 from the height H of about 30 to 40 degrees, preferably about 35 degrees; an instrument attachment means, 826, such as a tapped instrument attachment hole, is provided in the posterior face of the PLIF implant; this feature is best seen from the posterior view of FIG. 8G, which shows: an instrument attachment hole 826 having a diameter of about 1.5 to about 2.5 mm, preferably about 2 mm, and a depth of about 4-5 mm, preferably about 4.5 mm; an edge to center of the instrument attachment hole dimension 827 is carefully defined to match dimensions of any implant insertion device used in combination with this embodiment of the PLIF implant; a center of the instrument attachment hole to edge dimension 828 is about 4-6 mm, preferably about 5 mm, with a ridge 829 of about 1 mm running along three edges of the posterior face of the implant. In displaying the section A-A from ~~figure~~ FIG. 8D in ~~figure~~ FIG. 8E, a slight air gap 830 is shown as the section would exit bone on the concave surface of the implant and then reenter bone.

Please delete the paragraph beginning at page 19, line 2 of the specification, and substitute therefor the following paragraph:

In an analogous but alternate method for production of the cervical implant, unitary implants may be produced by appropriately sectioning and machining along the anterior margin of the tibia or linea aspera of the femur. Thus, as shown in ~~figure~~ FIG. 10A, a left femur 1000 (posterior aspect), or in ~~figure~~ FIG. 10B, a left tibia 1001 (anterior aspect), is sectioned at 1004 and 1005 to remove the head, neck and greater trochanter 1002 and internal and internal condyles 1006 of the femur, or tubercle and tuberosity 1003 and malleolus 1007 of the tibia. The result from such sectioning is the production of a shaft, or diaphysis, of the femur 1008 or tibia 1009. Further processing according to this aspect of the invention involves the ~~line asper~~ linea aspera 1010 of the femur or the anterior margin of the tibia 1011, as shown in ~~figure~~ FIG. 10C. Whether produced from the femur or tibia, a diaphysial shaft 1012, extending as shown at 1016 to a length permitted by the length of the shaft~~,~~ is produced by the sectioning at 1004/1005. The shaft comprises the natural intramedullary canal 1013. The thus produced shaft is then further sectioned in a plane shown at 1014 to produce a shaft of bone removed from the natural intramedullary canal 1013 having a cylindrical but somewhat triangular external shape. Into this shaft may be drilled a cannulation 1015, as shown in ~~figure~~ FIG. 11.

Please delete the paragraph beginning at page 20, line 13 and substitute therefor the following paragraph:

~~Figure 13~~ FIG. 13A shows a device similar to that of ~~figure 12~~ FIG. 12A, with a cancellous plug inserted therein. ~~Figure~~ FIG. 14 shows a device having a width W1 of about 14 mm and a height H1 of between about 5 mm and about 14 mm. ~~Figure 15~~ FIG. 15A shows a device similar to that of ~~figure 14~~ FIG. 14A with a cancellous plug inserted therein. ~~Figure~~

FIG. 16 shows a device having a width W1 of about 14 mm, a width W2 of about 14 mm, and a height of between about 5 mm and 11 mm. ~~Figure 17~~ FIG. 17A shows a device similar to that of ~~figure~~ FIG. 16A having a cancellous plug inserted therein. Table I below summarizes the various features and provides examples of specific dimensions for various embodiments of the implant of this invention shown in ~~figures~~ FIGS. 12-17:

Amendment to the Claims:

Please substitute the following listing of the claims for any prior set of claims

Claims 1-110 (Cancelled)

111. (currently amended) An assembled bone implant comprising:

a first cortical bone portion;

a second cortical bone portion;

said first cortical bone portion and said second cortical bone portion having one or more through holes sized and positioned for receiving one or more retention pins for connecting said first cortical bone portion to said second cortical bone portion; and

one or more retention pins of appropriate diameter for connecting said first cortical bone portion to said second cortical bone portion to form said assembled bone implant as a unitary body.

112. (currently amended) The assembled bone implant of claim ~~111~~ 113, wherein said first cortical bone portion and said second cortical bone portion each have a D shape.

113. (currently amended) The assembled bone implant of claim ~~112~~ 111, wherein said first cortical bone portion is stacked over said second cortical bone portion.

114. (Previously presented) The assembled implant of claim 112, wherein said retention pin is selected from the group consisting of cortical bone, a bioabsorbable synthetic polymer and titanium.

115. (Previously presented) The assembled implant of claim 114, wherein said retention pin is cortical bone.

116. (Previously presented) The assembled implant of claim 111, wherein said first cortical bone portion is a mirror image of said second cortical bone portion.

117. (Previously presented) The assembled implant of claim 112, wherein the graft has a beveled edge of defined radius.

118. (Previously presented) The assembled implant of claim 111, wherein said first cortical bone portion and said second cortical bone portion are in a stacked position relative to one another.

119. (Withdrawn) The assembled implant of claim 116, wherein said first cortical bone portion and said second cortical bone portion are in a side-by-side position.

120. (Previously presented) The assembled implant of claim 112, wherein said first cortical bone portion and said second cortical bone portion are allograft bone.

121. (Previously presented) The assembled implant of claim 112, sized and shaped in the form of a cervical implant.

122. (Previously presented) The assembled implant of claim 112, having a height between 7 and 14 mm.

123. (Previously presented) The assembled implant of claim 111, wherein said one or more retention pins comprise a cancellous bone portion.

124. (Previously presented) The assembled implant of claim 123, wherein said cancellous bone portion is treated with a bone morphogenetic protein (BMP).

125. (Previously presented) The assembled implant of claim 112, wherein said implant has two opposing surfaces that are inscribed with teeth.

126. (Previously presented) A D-shaped assembled bone implant for implantation into a patient comprising:

a first cortical bone portion having a D shape; and

a second cortical bone portion having a D-shape;

said first cortical bone portion and said second cortical bone portion being superimposed to form D-shaped implant having the combined thickness of said first cortical bone portion and said second cortical bone portion, said D-shaped implant having a through-hole sized and positioned for receiving a retention pin for retaining said first cortical bone portion to said second cortical bone portion in stacked formation.

127. (Previously presented) The assembled implant of claim 126, wherein said retention pin is a cortical bone pin.

128. (Previously presented) The assembled implant of claim 126, wherein said retention pin is a cancellous bone portion is treated with a bone morphogenetic protein.

REMARKS

The amendment to the specification does not add new matter. The amendments to the description of the Figures were made at the request of the Examiner and reflect the plurality of the Figures. Specifically, the description of FIG. 1 has been amended to recite that FIGS 1A-1D provide several views of "a substantially 'D'-shaped cortical bone implant." Support for this amendment is found throughout the specification, including at page 9, line 14 ("Referring now to figure 1A, there is shown a top view, as if viewed from the top of the spinal column, of **a substantially 'D'-shaped cortical bone implant 100**."); at page 9, line 19 ("In figure 1B, there is shown a side view of the implant, 100 . . . ."); at page 9, line 23 ("In figure 1C, there is shown a top view of the implant, 100 . . . ."); and at page 9, line 25 ("Figure 1D shows a top view of the implant, 100. . . ."). In addition, FIG. 1 has been amended to recite that "FIG. 1E shows the detail of the inscribed feature of FIG. 1D." Support for this amendment is found in the specification at FIGS. 1D-1E and in the specification at page 9, lines 30-31 ("In figure 1E, there is shown a detail of one embodiment of the inscribed feature 120 on the portion of the implant indicated in figure 1D.").

The description FIG. 2 has been amended to reflect that FIGS. 2A and 2B provide "side and end-on views, respectively." Support for this amendment is found in FIGs. 2A and 2B, and in the specification at page 10, lines 17-19 ("Referring to figure 2, there is shown in **side view in figure 2A** a core cutter 200, having a core bit 201 which is affixed by a set screw 203 to the shaft 204 of a drill bit 202, centrally located within and coaxial with the core cutter. In **figure 2B**, an **end-on view** of the core cutter 200. . . .").

The description FIG. 3 has been amended to reflect that FIG. 3B provides an "**end-on view**" of an asymmetric canal "**in a cancellous bone plug.**" Support for the description is found in FIG. 3B and in the specification at page 11, lines 2-4 ("In figure 3B, there is provided an **end-on view** of the **cancellous bone plug** 310 after the broaching procedure is completed. As can be seen, the internal canal 104 has been converted from a circular canal into a substantially 'D'-shaped canal."); emphasis added in bold.

The description of FIG. 4 has been amended to refer to "FIGs. 4A-4E." Support for "FIGS 4A-4E" is found in "FIGs 4A-4E" themselves.

The description of FIG. 5 has been amended to separately refer to FIGs. 5A-5E. Support for FIG. 5A being a "**top**" view is found in FIG. 5A and in the specification at page 14, line 25 ("In figure 5, figure 5A, there is provided a **top** view of one side of one embodiment of the blades 502 used for the broach assembly."); emphasis added in bold. Support for the amendment that "FIG. 5B is a **side-view** of a implant mounting device having a "**D"-shaped cavity**" is found in the specification at page 15, lines 3-5 ("In FIG. **5B,** there is provided a **side view** of an implant mounting device 504 having a **"D"-shaped cavity** 505 into which a "D"-shaped implant may be fitted for passage through the opposing jaws of the broaching jaw apparatus 500"); emphasis added in bold.] Support for the amendment reciting that "FIGS. 5C-5E provide **views of an alternate apparatus and method for fashioning the retention teeth in an implant**" is found in the specification at page 15, lines 7-8 ("In FIGS. 5C-5E, there is shown **views of an alternate apparatus and method for fashioning the retention teeth in the implant**."); emphasis added in bold.

The amendment to the description of FIG. 6, which recites "FIGS. 6A-6C, 6D-6F and 6G-6I, respectively, provide several views and dimensions for **three** specific embodiments of an implant of this invention," is supported by the disclosure in FIGS 6A-6I and the disclosure in the specification at page 16, lines 3-4 ("In FIG. 6A-I, there is provided a view of **three** different cortical bone implants according to this invention having particular geometries by way of example and not limitation.").

The amendment to the description of FIG. 7, which recites that "FIG. 7A is **a top view of an implant into which four holes have been drilled,**" is supported throughout the specification, including at page 16, lines 26-27 ("The embodiment shown in FIG. 7A is **a top view of an implant 700 into which four holes 701-704 have been drilled.**"); emphasis added in bold. The amendment to the description of FIG. 7, which recites that "FIG. 7B provides a side view of a stacked embodiment of **two** implants of FIG. 7A of this invention **shown in juxtaposition,**" is supported throughout the specification, including at page 16, lines 28-30 ("In FIG. 7B, there is shown the

juxtaposition of **two** implants **700A** and **700B**, with the drilled holes 701-704 in register to receive pins for maintaining the implants in register"); and at page 16, lines 13-16 ("In **FIG.** 7, there is shown a further aspect of this invention in which an implant, either machined as described above, or prior to said machining, is further machined so as to allow **stacking** thereof to achieve implants of various heights.").

The description of FIG. 8, which has been amended to recite that "FIGS. 8B and 8C shows the implants of the invention **in bone stock**," is supported by the disclosure in FIGS. 8B and 8C, and by the disclosure in the specification at page 17, lines 27-29 ("In such a case, a device 810, such as that shown in FIGS. 8D-8G is machined from **bone stock as shown in FIGS. 8B, 8C** or another appropriate bone stock . . ."); emphasis added in bold. The description of FIG. 8, which has been amended to recite that "FIGS. 8D-8G show "several views" of an embodiment useful for posterior lumbar intervertebral fusion procedures (PLIFs), is supported by the showing of several views in FIGS. 8D-8G.

The description of FIG. 10, which has been amended to associate FIG. 10B with the tibia, and FIG. 10A with the femur, is supported by the disclosure in the respective figures and by the disclosure in the specification at page 19, lines 5-6 ("Thus, as shown in figure 10A, a left femur 1000 (posterior aspect), or in FIG. 10B, a left tibia 1001 (anterior aspect), is **sectioned at 1004**. . .") The description of FIG. 10, which has been amended to recite that FIG. 10C shows a "**section**" of long bone, is supported by the disclosure in FIG. 10C, showing section line **1004**, and at page 19, lines 9-13 ("Further processing according to this aspect of the invention involves the linea aspera 1010 of the femur or the anterior margin of the tibia 1011, as shown in **figure 10C**. Whether produced from the femur or tibia, a diaphysial shaft 1012, extending as shown at 1016 to a length permitted by the length of the shaft produced by the **sectioning** at **1004**/1005.").

The description of FIG. 11, which has been amended to refer back to the bone of FIG. 10C, is supported by the disclosures in FIGS. 10C and 11, and by the disclosure in the specification at page 19, lines 14-17 ("The thus produced shaft [from FIG. 10C] is then further sectioned in a plane shown at 1014 to produce a shaft of bone removed from the natural intramedullary canal 1013 having a cylindrical but somewhat triangular

external shape. Into this shaft may be drilled a cannulation 1015, as shown in FIG. 11.")

The description of FIG. 12, which has been amended to describe FIGS. 12A-12D as providing a "**top**" view, a "**side**" view, a "**detail view of the grooves which angle toward the posterior of the implant**," and a "**sectional**" view, respectively, is supported by the disclosure in those respective figures, and by the disclosure in the specification at page 20, lines 1-5 ("Per FIGS. 12-17, there is provided views of five different cortical bone implants according to this invention having particular geometries by way of example and not limitation. In each figure, view A is a **top** view, view B is a **side** view, view C is a **detail of the grooves which angle toward the posterior aspect of the implant**, and view D is a **sectional** view through the line A-A shown in view A."); emphasis added in bold.

As cited above, FIGs 12-17 have these identical views. See the specification at page 20, lines 1-5 ("Per FIGS. 12-17, there is provided views of five different cortical bone implants according to this invention having particular geometries by way of example and not limitation. In each figure, view A is a **top** view, view B is a **side** view, view C is a **detail of the grooves which angle toward the posterior aspect of the implant**, and view D is a **sectional** view through the line A-A shown in view A."); emphasis added in bold. In addition, the specification discloses that for FIGS 13E-13F, 15E-15F and 17E-17F, that each of FIGS. E and F are a "top view and a "side" view of a cancellous plug that appears in the central canal in each of these implants. See the specification at page 20, lines 5-6 ("In addition, where an osteogenic plug, such as a cancellous plug is present, this is shown in view E as a top view and view F as a side view of the cancellous plug.")

The amendment to the paragraph of the specification beginning at page 14, line 25, deletes the double recitation of "figure" and replaces with "FIG." Elsewhere in the paragraph, figure was replaced with "FIG."

The amendment to the paragraph, beginning at page 17, line 24, corrects the obvious error in the recitation of the view of the implant of FIG. 8D (showing rows of ridges, projections or teeth) from "side" view to "top" view. The specification discloses

that only the top or bottom surfaces, or both, of the implant have projections, teeth or grooves. See the specification at page 7, lines 23-26 ("In addition, **other external profiles** than the "D"-shaped profile are likewise **enabled** by **modifications of the methods and apparatuses disclosed herein for formation of the "D"-shaped external** or internal **profile.**"); page 8, lines 20-22 ("**Shapes** contemplated by this disclosure include, but are not limited to, elliptical shapes, D-shapes, **partially curved shapes**, and the like."); and at page 8, lines 27 to page 9, line 2 ("or an external feature may be machined into the upper and lower surfaces to prevent backing out of the implant upon insertion into the intervertebral space. This may be achieved by a number of means, such as by machining annular rings, indentations and **projections, ribbing or teeth** into the **upper, lower, or both surfaces** of the implant. In a preferred embodiment of this invention, the implant is passed through a set of opposing jaws bearing teeth which broach a tooth-shaped profile into the implant as it is forced through the jaws. Alternatively, the implant is passed several times over a ridged surface which cuts the desired tooth profile into the **upper, lower or both surfaces** of the implant.")

The amendment to the paragraph, beginning at page 19, line 2, corrects the typographical error in line 8 of that paragraph from "line asper" to "linea aspera". Support for the correct spelling of the term "linea aspera" is found in the same paragraph at line 3 therein. Additional recitation of "linea aspera" is found in the original description of the figures at page 3, line 17.

The amendment to the paragraph beginning at page 20, line 13 does not add new matter. The paragraph changes the term "figure" to "FIG" at relevant locations. In addition, the amendments to the paragraph more specifically refer to the "A" component of the figures rather than to figures by number only.

For all these reasons, the amendments to the specification do not add new matter.

The amendments to the claims do not add new matter. Claim 111 has been amended to recite as follows: "one or more retention pins <u>of appropriate diameter</u> for connecting said first cortical bone portion to said second cortical bone portion to form

said assembled bone implant as a unitary body." Support for the retention pins being of "appropriate diameter" for connecting said first cortical bone portion to said second cortical bone portion to form said assembled bone implant "as a unitary body," is found in the specification at page 18, line 27 to page 19, line 2 ("Pins, composed of cortical bone, resorbable but strong biocompatible synthetic material, or metallic pins of the **appropriate diameter** are then impelled into the holes in the implants such that the implants **are formed into a unitary body by these pins.**"). Thus, the "pins" of appropriate diameter form the Applicants' unitary body – not an adhesive such as disclosed in Siebels. Support for the pins being called "retention pins" is found throughout the specification, including at page 5, lines 15-16 ("appropriate **retention pins** made from any desirable material, including cortical bone, bioabsorbable synthetic polymer, titanium and other metallic retention pins"); emphasis added in bold.

Thus, the amendments to the claims do not add new matter.

Summary of the Bases for Rejection/Objection

Claims 111-118 and 120-128 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting over all claims in USSN 10/375,540.

Claims 111-118 and 120-128 are rejected under 35 U.S.C. § 103(a) over U.S. Pat. 5,989,289 (Coates) in view of EP 517030 (Siebels).

The Applicants will answer each of these bases for objection in Sections I-II which follow.

I. Obviousness-type Double Patenting

Claims 111-118 and 120-128 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting over all claims in co-pending sister application USSN 10/375,540. No claims have been deemed allowable in the present application or in co-pending sister application USSN 09/722,205. The Applicants will address the issue when it becomes ripe as when one or more claims become allowable in

either application.

II. 35 U.S.C. § 103(a)

Claims 111-118 and 120-128 are rejected under 35 U.S.C. § 103(a) over U.S. Pat. 5,989,289 (Coates) in view of EP 517030 (Siebels). According to the Patent Office, "[r]eferring to all figures, Coates teaches a D-shaped cortical bone spinal implant. . . ." [Official Action at pages 2-3 citing to Coates at col. 11, lines 42 et seq.] The Patent Office admits that "**Coates et al fails to teach said implant can comprise a first and second portion capable of being connected by a pin**." [Official Action at page 3; emphasis added in bold.] To make up for this deficiency, the Patent Office cites to Siebels, stating that Siebels discloses "a spinal implant and teaches stacking portions 11 of the implant and connecting said portions 17." [Official Action at page 3.] The Patent Office then concludes that "[i]t would have been obvious to one skilled in the art to have utilized the teachings of Siebels to stack and connect the individual implant portions with the D-shaped cortical bone implant of Coates wherein multiple portions could be stacked and connected by at least one pin in corresponding through holes to adjustably build the implant to a desired height (thickness) to best fill the disk space as desired by the surgeon." [Official Action at page 3.] The Applicants respectfully disagree.

Reason #1

"It is impermissible within the framework of section 103 to pick and choose from any one reference only so much of it as will support a given position, to the exclusion of other parts necessary to the full appreciation of what such reference fairly suggests to one of ordinary skill in the art." *See Bausch & Lomb, Inc. v. Barnes-Hind Int'l, Inc.*, 230 USPQ 416, 420 (Fed. Cir. 1986), *quoting In re Wesslau*, 147 USPQ 391, 393 (CCPA 1965) In the present case, the Applicants object to the Patent Office's citation to Siebels, which is a foreign reference that is totally in the German language without also providing the translation of that document. As stated in the MPEP at §901.06(a), such

translations are available to the Examiner ("Examiners may also request written translations of pertinent portions of references being considered for citation or already cited in applications."). Moreover, only the odd pages of Siebels were photocopied by the Patent Office and provided to the Applicants. (Siebels was apparently a double-sided document.) In making its rejection, the Patent Office cites to Siebels and circles German words such as "Stifte 17," "Ende 18" and "Bohrungen 16" at page 3, col. 2, lines 50-58. However, the term "Stifte 17" as circled by the Patent Office at page 3, col. 2, line 56 is actually the shortened form of the antecedent term "Verankerungs**stifte** 17" of the prior sentence. Notice that both have the same number "17." Thus, the Patent Office is relying upon a shortened and more colloquial use of the more complete term "Verankerungs**stifte** 17". No translation or reference to any dictionary definition is given for any word—whether "Stifte 17" or the complete term "Verankerungs**stifte** 17" which was **not** relied upon by the Patent Office. Moreover, referring to Figure 1 of Siebels, it is noted that Ende 18 and Ende 19 (page 3, col. 2, lines 50-58) appear to point to the same structure as Verankerungs**stifte** 17. However, even if a translation of the relevant terms were given, there is **no context** for the words, such as would be provided by a translation of the entire reference, which would give a full appreciation to what the reference teaches to one of ordinary skill in the art. *See Bausch & Lomb, Inc. v. Barnes-Hind Int'l, Inc.*, 230 USPQ at 420. For this reason, the German language reference, Siebels, and its obscure figure are not properly citable as prior art without a translation of the relied upon terms (in their unabbreviated form) and in the context in which they are used.

Reason #2

The combination of Coates and Siebels would fail to make a *prima facie* case of obviousness for a plurality of reasons. A translation of a sentence at page 3, col. 1, lines 22-26 in Siebel that uses the term "CFK" discloses that the device of Siebels is made of "plastic:"

Die Scheiben werden vorzugsweise aus einem

> kohlenstoffaserverstärkten Kunststoff (CFK) hergestellt, wobei die Verankerungsmittel je nach Ausgestaltung des Implantats aus demselben oder einem anderen Material bestehen können.
>
> [Siebels at page 3, col. 1, lines 22-26.]
>
> * * *
>
> The disks are produced preferably out of a kohlenstoffaserverstärkten plastic (CFK) whereby the anchorage means can consist according to arrangement of the implant of that or of one other material.
>
> [Exhibit A: English translation from the website www.ets.freetranslation.com of Siebels at page 3, col. 1, lines 22-26.]

A translation of another sentence in Siebels that uses the term "Zement" discloses that the device of Siebels requires the use of an adhesive ("Zement") to "appropriately" hold the disks together as a "solid unit":

> In jeder Ausführung ist es möglich, die Scheiben zu einer soliden Einheit miteinander zu verkleben, z.B. mit PMMA-Zement, wenn erforderlich oder zweckmäßig.
>
> [Siebels at page 3, col. 1, lines 18-21.]
>
> * * *
>
> In each execution, it is possible to paste the disks to a solid unit together, with PMMA-cement, if required or appropriately.
>
> [Exhibit B: English translation from the website www.ets.freetranslation.com of Siebels at page 3, col. 1, lines 18-21.]

"PMMA," as used above, is known to those skilled in the medical art as the acronym for the biocompatible adhesive "polymethylmethacrylate." See U.S. Pat. 5,127,920 at col. 4, lines 20-24 ("The most commonly accepted method of fixing the femoral component to the

femur is by polymethyl methacrylate (PMMA). PMMA is a two-component acrylic cement which has the advantage of exhibiting a rapid setting time."); emphasis added in bold. Thus, the device of Siebels is made of plastic and uses an adhesive to hold it together.

Moreover, referring to the device in Fig. 1 of Siebels, the Verankerungsstifte 17 are shown as having **two ends of differing diameters**. In Fig. 1, the Ende 18 (first end) is shown as having a larger diameter than the Ende 19 (other end) which has a smaller diameter. This is apparent in Fig. 1 as the greater black space between the side walls of Ende 19 and the hole into which it is inserted. Only Ende 18 is connected to the stacking portion 11 while the other end (Ende 19) with its smaller diameter merely provides a segment for alignment of the next stacking portion. This allows the disks to be readily stacked in surgery and the heights adjusted by quick assembly without a major construction project of inserting four Verankerungsstifte 17 (PTO's pins) per stacking portion. Consistent with this, Siebels states that each stacking portion 11 is "connected" at end 18 of each Verankerungsstifte 17, whereas end 19 "juts in" a slight distance into the hole in the stacking portion 11 above:

> Gemaß der Ausführung nach Fig 1 sind die Stifte 17 mit ihrem jeweils einem Ende 18 mit einer Scheibe 11, 13 verbunden, während sie mit dem anderen Ende 19 in die Bohrung einer nächsten Scheibe 11 hinein ragen. Bei dieser Ausgestaltung wird eine Endescheibe 14 ohne Stift auszugestalten sein.
>
> [Siebels at page 3, col. 4, line 55 to page 4, col. 5, line 3.]
>
> * * *
>
> Gemaß of the execution after Fig 1 **connected the pencils [pegs] 17 with its respectively an end 18** with a disk 11, 13 while they **jut** with **the other end 19** into the Bohrung of a **next** disk 11 **in.** In this arrangement, an end disk 14 will be, to arrange without pencil.
> [Exhibit C: English translation from www.ets.freetranslation.com of Siebels at page 3, col. 4, line 55 to page 4, col. 5, line 3; emphasis added in bold.]

Thus, the thinner diameter end 19 of the Verankerungsstifte 17 of Siebels merely "jut in" holes of the "**next**" disc above for alignment, whereas the thicker diameter end 18 of the Verankerungsstifte 17 are "connected" to the holes of the lower disk 11. In contrast, the retention pins of claim 111 of the present invention are connected to both a first cortical bone portion and a second cortical bone portion "to form a unitary implant". In Siebels, the implant is not a unitary implant unless the disks are glued together. *See* the discussion supra. For this reason and all of the above reasons, the combination of Coates and Siebels would have failed to render obvious claims 111-118 and 120-128 at the time that the Applicants' invention was made.

CONCLUSION

The provisional rejection of all claims of this restricted invention for double patenting over all claims of a separately restricted sister application will be address at such time as claims in one of the applications has been allowed. The rejection of claims 111-118 and 120-128 under 35 U.S.C. § 103(a) over U.S. Pat. 5,989,289 (Coates) in view of EP 517030 (Siebels) has been overcome by the showing of facts and the arguments herein. The allowance of claims 111-118 and 120-128 is respectfully requested.

Respectfully submitted,

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duty; *städtische*: rate; ~be-amte(r) *m* revenue-officer; ~berater (-bᵉ-rāhtᵉr) *m* tax-expert; ~bord ⚓ *n* starboard; ~erhebung (-ĕrhébōōng) *f* levy(ing of taxes); ~erklärung (-ĕrklärōōng) *f* (income-) tax return; ~ermäßigung (-ĕrmäsigōōng) *f* allowance; ⁓frei (-frī) tax-free; *Ware*: duty-free; ~freiheit *f* exemption from taxation; ~hinterziehung (-hintᵉrtseeōōng) *f* tax evasion; ~kasse *f* tax-collector's office; ~mann *m* helmsman; ⁓n steer, *bsd.* pilot; *mot.* drive; ⊕ control; e-r S. ~ check a th.; ⁓pflichtig (-pfliçtiç) taxable; *Sache*: dutiable; ~politik (-pŏliteek) *f* fiscal policy; ~rad (-rāht) *n* (steering)wheel; ~ruder (-rōōdᵉr) *n* rudder, helm; ~satz (-zāhts) *m* rate of assessment; ~ver-anlagung (-fĕrāhnlāhgōōng) *f* assessment; ~zahler (-tsāhlᵉr) *m* taxpayer; ratepayer.

Ste'ven (shtévᵉn) ⚓ *m* stem.

Stich (shtiç) *m* (*Nadel*⁓) prick; *e-s Insekts*: sting; (*Dolch*⁓) stab; (*Näh*⁓) stitch; *Karten*: trick; (*Kupfer*⁓) engraving; ⚕ (*Seiten*⁓) stitch; ~ *halten* hold good; *im* ~ *l.* desert; forsake.

Stichel|ei' (shtiçᵉlī) *f*, ⁓'n taunt, sneer.

Sti'ch|flamme *f* darting flame; ⁓haltig valid, sound; ~probe (-prōbᵉ) *f* random test *od.* sample; ~tag (-tāhk) *m* fiexd day, key-day; ~wahl *f* second ballot; ~wort *n* catchword; *thea.* cue; ~wunde (-vōōndᵉ) *f* stab.

sti'cken (shtikᵉn) embroider.

Stickerei' (shtikᵉri) *f* embroidery.

Sti'ck|garn *n* embroidery-cotton; ~husten (-hōōstᵉn) *m* (w)hooping-cough; ⁓ig suffocating; *Luft*: close, stuffy; ~stoff ⚗ *m* nitrogen.

stie'ben (shteebᵉn) (sn) fly (about).

Stie'f... (shteef-): *mst* step ...; *z. B.* ~bruder (-brōōdᵉr) *m* stepbrother.

Stie'fel (shteefᵉl) *m* boot; ~bürste *f* boot-brush; ~knecht *m* boot-jack; ~putzer (-pōōtsᵉr) *m in Hotels*: boots; *auf der Straße*: shoeblack; ~schaft *m* leg of a boot; ~wichse (-viksᵉ) *f* blacking, boot-polish.

Stie'f|mutter (steefmōōtᵉr) *f* step-mother; ~mütterchen (-mütᵉrçᵉn) ⚘ *n* pansy; ~vater (-fāhtᵉr) *m* stepfather.

Stiel (shteel) *m* handle, helve, haft; (*Besen*⁓) stick; ⚘ stalk.

Stier (shteer) *m* bull; ⁓'en stare (*auf acc. nach* at).

Stift (shtift) 1. *m* pin; peg; (*Zwecke*) tack; (*Zeichen*⁓) pencil, *farbiger*: crayon; F (*Lehr*⁓) youngster; 2. ~ *n* (charitable) foundation; ⁓'en found; establish; (*spenden*) give, *Am.* donate; (*verursachen*) cause; *Frieden*: make; ~'er(in *f*) *m* founder; donor; (*Urheber*) author.

Sti'ftung (-ōōng) *f* foundation; establishment; ~sfest *n* founder's day.

Stil (shteel) *m* style; ⁓'gerecht stylish; ⁓isie'ren (-izeerᵉn) compose, word, stylize; ⁓i'stisch stylistic.

still (shtil) still, quiet; (*schweigend*) silent; *Luft, See, Gefühl*: calm; ✝ dull, flat; (*heimlich*) secret; ~! silence!; *im* ~*en* in secret; ✝ ~*er Gesellschafter* sleeping (*Am.* silent) partner; *der* ⁓*e Ozean* the Pacific (Ocean); ⁓'e *f* stillness; silence, calm(ness); ~'egen (shtil-léghᵉn) *Betrieb*: shut down; ~'en *Schmerz*: still; *Zorn, Hunger*: appease; *Blut*: stanch; *Durst*: quench; *Kind*: nurse; *Begierde*: gratify; ~'halten keep still; (*einhalten*) stop; ~'iegen (shtil-leeghᵉn) lie still; *Betrieb*: be idle.

sti'llos (stullōs) without style.

sti'll|schweigend (shtilshvīghᵉnt) silent; *fig.* tacit; ⁓stand *m* standstill; ~stehen (-shtéᵉn) stand still; *fig.* be at a standstill; ⚔ ⁓*gestanden!* attention!

sti'lvoll (shteelfŏl) stylish.

Sti'mm|band (shtimbāhnt) *n* vocal c(h)ord; ⁓berechtigt (-bᵉrĕçtikt) entitled to vote; ~e *f* voice; (*Wahl*⁓) vote; (*Presse*⁓) comment; ♪ (*Noten*) part; ⁓en *v/t.* tune; *fig. günstig usw.*: dispose; *v/i.* agree; *bei der Wahl*: vote; F *das stimmt* (that is) all right; ~enmehrheit *f* majority (*Am.* plurality) of votes; ~-enthaltung *f* abstinence from voting; ~enzählung *f* counting of votes; ~gabel (-gāhbᵉl) *f* tuning-fork; ~recht *n* right of voting; ~ung *f* ♪ tune; *fig.* mood, humour; ⁓ungsvoll (shtimōōngsfŏl) impressive; ~zettel *m* voting-paper.

sti'nken (shtingkᵉn) stink.

Stipe'ndium (shtipĕndⁱōōm) *n* scholarship; exhibition.

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In jeder Ausführung ist es möglich, die Scheiben zu einer soliden Einheit miteinander zu verkleben, z.B. mit PMMA-Zement, wenn erforderlich oder zweckmäßig.

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German to English

Gemaß der Ausführung nach Fig 1 sind die Stifte 17 mit ihrem jeweils einem Ende 18 mit einer Scheibe 11, 13 verbunden, während sie mit dem anderen Ende 19 in die Bohrung einer nächsten Scheibe 11 hinein ragen. Bei dieser Ausgestaltung wird eine Endescheibe 14 ohne Stift auszugestalten sein.

a e i o u Other

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/905,683	07/16/2001	Jamie M. Grooms	197319US/222962US	4376

7590 12/15/2004

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EXAMINER	
SNOW, BRUCE EDWARD	
ART UNIT	**PAPER NUMBER**
3738	

DATE MAILED: 12/15/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)
	09/905,683	[illegible]OOMS ET AL.
	Examiner	**Art Unit**
	Bruce E Snow	3738

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 September 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *111-128* is/are pending in the application.

4a) Of the above claim(s) *119* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *111-118 and 120-128* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)

2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *10/29/04*.

4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .

5) ☐ Notice of Informal Patent Application (PTO-152)

6) ☐ Other: _____.

DETAILED ACTION

Response to Arguments

Applicant's arguments filed 9/20/04 have been fully considered. The Examiner is including a copy of the translation of Siebels (EP 517030) as requested as attachment A. This Office action is non-final.

Double Patenting

All claims are provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of all claims of copending Application No. 10/375,540. This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 117 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding claim 117, "graft" lacks antecedent basis.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 111-118, 120-123, 126-127 are rejected under 35 U.S.C. 102(b) as being anticipated by Albee (Bone Surgery with Machine Tools).

Referring to all figures, specifically figures 10-12 and 15, Albee teaches:

a first cortical bone portion;

a second cortical bone portion;

said first cortical bone portion and said second cortical bone portion having one or more through holes sized and positioned for receiving one or more retention pins for connecting said first cortical bone portion to said second cortical bone portion; and

one or more retention pins of appropriate diameter for connecting said first cortical bone portion to said second cortical bone portion to form said assembled bone implant unitary body.

Regarding figures 11-12, Albee teaches superimposed first and second cortical bone portions each have a D-shape having a through hole with receives the I shaped pin interpreted as having an appropriate diameter. Albee teaches the pines are grafts which inherently comprise cortical and cancellous bone.

Regarding claim 116, mirror image, see at least figure 15.

Regarding claim 121, the embodiments shown in figures 11-12 are sized and shaped for in the form of a cervical implant.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 111-118 and 120-128 are rejected under 35 U.S.C. 103(a) as being unpatentable over Coates et al (5,989,289) in view of Siebels (EP 517030).

Referring to all figures, Coates teaches a D-shaped cortical bone spinal implant (see column 11, lines 42 et seq.). However, Coates et al fails to teach said implant can comprise a first and second portion capable of being connected by a pin. Siebels also teaches a spinal implant and teaches stacking portions 11 of the implant and connecting said portions with pins 17. It would have been obvious to one having ordinary skill in the art to have utilized the teachings of Siebels to stack and connect individual implant portions with the D-shaped cortical bone implant of Coates wherein multiple portions could be stacked and connected by at least one pin in corresponding through holes to adjustably build the implant to a desired height (thickness) to best fill the disc space as desired by the surgeon.

Regarding at least claims 114-115, 123, and 127, lacking any criticality in the specification, the use of the claimed materials such as titanium in lieu of those taught by Seibels produce no advantage and is considered an obvious matter of design choice. Additionally, Coates teaches the use of metal devices are foreign bodies which can never be fully incorporated in the fusion mass and produce stress shielding because the stiffness values do not match that of bone (column 2, lines 34 et seq.). Therefore, it would have been obvious to one having ordinary skill in the art to have constructed the

pin out of cortical bone or cancellous bone which can be fully incorporated and does not produce stress shielding.

Regarding claim 122, see column 11, lines 62 et seq.

Regarding claims 124 and 128, Coates et al teaches treating the spacer with BMP which would include the pins.

All other claimed limitations are self-evident.

Claims 111-118 and 120-128 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brantigan (5,192,327) in view of Coates et al (5,989,289).

Referring to all figures, specifically figures 2 and 5, Brantigan teaches a D-shaped bone implant comprising:

a first portion 21;

a second portion 21;

said first portion and said second portion having one or more through holes 24 sized and positioned for receiving one or more retention pins 15 for connecting said first cortical bone portion to said second cortical bone portion; and

one or more retention pins of appropriate diameter for connecting said first cortical bone portion to said second cortical bone portion to form said assembled bone implant unitary body.

However, Brantigan fails to teach the first and second portions are cortical bone. Brantigan teaches the device can be made of traditional orthopaedic implant materials; see the abstract. Coates et al teaches a D shaped implant can be made of cortical

bone. It would have been obvious to one having ordinary skill in the art to have utilized cortical bone which is a traditional orthopaedic implant material as taught by Coates for any of the elements of Brantigan because "*5,192,327 to Brantigan teach hollow metal cage structures. Unfortunately, due to the stiffness of the material, some metal implants may stress shield the bone graft, increasing the time required for fusion or causing the bone graft to resorb inside the cage. Subsidence, or sinking of the device into bone, may also occur when metal implants are implanted between vertebrae if fusion is delayed. Metal devices are also foreign bodies which can never be fully incorporated into the fusion mass.*" See column 2, lines 40 et seq. of Coates.

Regarding at least claims 114-115, 123, and 127, the combination at least teaches titanium or cortical bone, lacking any criticality in the specification, the use of the specific use of any claimed materials for the pin in lieu of those taught by references produces no advantage and is considered an obvious matter of design choice. Additionally, Coates teaches the use of metal devices are foreign bodies which can never be fully incorporated in the fusion mass and produce stress shielding because the stiffness values do not match that of bone (column 2, lines 34 et seq.). Therefore, it would have been obvious to one having ordinary skill in the art to have constructed the pin out of cortical bone or cancellous bone which can be fully incorporated and does not produce stress shielding.

Regarding claims 124 and 128, Coates et al teaches treating the spacer with BMP which would include the pins.

All other claimed limitations are self-evident.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bruce E Snow whose telephone number is (571) 272-4759. The examiner can normally be reached on Mon-Thurs.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on (571) 272-4754. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

bes

BRUCE SNOW
PRIMARY EXAMINER

Attachment A

Europäisches Patentamt
European Patent Office
Office européen des brevets

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(54) **Wirbelkörperimplantat.**

(57) Als Implantat für Wirbelsäulen wird eine Scheibe (11) vorgeschlagen, die alleine oder zu mehreren gestapelt (11 bis 14) zwischen Wirbelkörper einsetzbar sind. Einzelne Scheiben werden nach Bedarf von einem Strang abgeschnitten, wobei die Scheibendicke dem Einzelfall genau angepaßt werden kann. Diese Implantate eignen sich insbesondere für Halswirbel sowie als Ersatz nach der Entfernung von Bandscheiben. Für die Bildung eines Implantats aus mehreren übereinandergestapelten Scheiben kann ein entsprechendes Sortiment von Scheiben bereitgestellt werden, die sich sowohl im Durchmesser als auch in der Höhe unterscheiden. Für den jeweiligen Anwendungszweck werden demzufolge Scheiben mit entsprechender Dicke ausgesucht und zusammengesetzt, so daß sie insgesamt die erforderliche Höhe des Implantats ergeben. Verschraubungen und insbesondere längere Handhabungen im eingesetzten Zustand des Implantats sind bei dem erfindungsgemäßen Implantat nicht erforderlich.

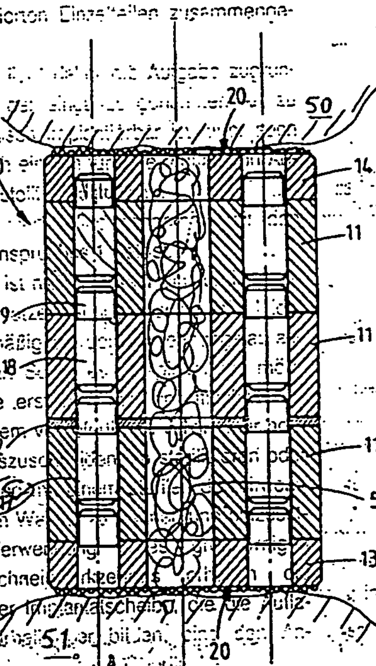

Fig.1

S?ile

EP 0 517 030 A2

Die Erfindung bezieht sich auf ein Implantat für Wirbelsäulen, bestehend aus mindestes einem steifen Element.

Wirbelkörper haben entlang einer Wirbelsäule unterschiedliche Größen und sind von Patient zu Patient auch unterschiedlich. Beim Ersetzen eines Wirbelkörpers durch ein Implantat ist es daher notwendig, das Implantat an die effektive Dimension des Abstandes zwischen den angrenzenden Wirbelkörpern anzupassen.

Umdiesen Umstand Rechnung zu tragen, wurden Implantate entwickelt (DE 30 23 942 C3), die aus im wesentlichen zwei in Schraubenverbindung stehenden Teilen bestehen, und deren axiale Höhe durch Drehen verändert bzw. an den Abstand zwischen den Wirbelkörpern angepaßt werden kann. Mittels Querschrauben oder anderen Verankerungsmitteln werden die beiden Teile nach ihrer Einstellung drehsicher verankert. Damit läßt sich zwar mittels einer Ausführung eine ganze Bandbreite von Abständen abdecken, aber die Höheneinstellung nimmt jedoch insbesondere bei einem feinen Gewinde relativ viel Zeit in Anspruch.

Diesen Nachteil behebend, ist aus der WO 90/00037 ein Implantat der gattungsgemäßen Art bekanntgeworden, das mittels eines Werkzeugs lediglich zwischen zwei Wirbel eingeschoben wird. Das annähernd quaderförmige Implantat wird jedoch aus komplizierten Einzelteilen zusammengesetzt.

Der Erfindung liegt daher die Aufgabe zugrunde, ein Implantat der eingangs genannten Art zu entwickeln, das rasch implantierbar ist, aber auch fertigungstechnisch einfach für eine Vielfalt von Abmessungen hergestellt werden kann.

Die Aufgabe wird erfindungsgemäß mit den Merkmalen des Anspruches 1 gelöst.

Eine Scheibe ist nicht nur sehr einfach in einen Wirbelspalt einzusetzen, sondern auch sehr leicht und dimensionsmäßig auf den Anwendungsfall angepaßt herstellbar. So ist es beispielsweise möglich, die Scheibe erst bei einer spezifischen Anwendung aus einem vorgefertigten vollen oder hohlen Strang herauszuschneiden, zu sterilisieren oder im sterilen Zustand mit einem sterilen Schleifwerkzeug und sterilem Wasser zu trennen und einzusetzen. Durch Verwendung eines grobkörnigen Schleif-bzw. Schneidwerkzeuges erhalten die Schnittflächen der Implantatscheibe, die die Auflagen für die Wirbelkörper bilden, eine den Anwachsprozeß fördernde rauhe Oberfläche.

Im Prinzip ist die Verwendung einer Scheibe jeder Konfiguration, rund, mehreckig, unregelmäßige Kontur möglich. Auch die innere Kontur einer ringförmigen Scheibe kann nach Bedarf gestaltet werden.

Die für den angrenzenden Wirbelkörper dienende Auflagefläche einer Scheibe ist zur Förderung des Anwachsprozesses strukturiert, rauh oder in unterschiedliche Richtungen gewählt ausgebildet. Verankerungsmittel in der Form von herausragenden Spitzen dienen der sofortigen Sicherung der Prothese nach der Implantation.

Das scheibenförmige Implantat wird vorzugsweise aus faserverstärktem Kunststoff hergestellt. Für ein einteiliges Implantat wird gemäß einer bevorzugten Ausgestaltung der Erfindung die Scheibe aus einem hohlen Strang herausgeschnitten, der aus einer Vielzahl von Flechtlagen besteht. Die Flechtlagen werden nacheinander auf einen entsprechend geformten Dorn, vorzugsweise auf einen Dorn mit rechteckigem Querschnitt und abgerundeten Ecken direkt in einer Flechtmaschine aufgezogen. Die Scheiben werden mit der gewünschten Höhe, die über die Scheibe variieren kann, abgeschnitten. Derartige Implantate zeichnen sich durch ihre außerordentlich leichte Herstellbarkeit aus, bei der die Faserorientierungen gleich eine optimale Steifigkeit und Festigkeit des Implantats bewirken.

Gemäß einer weiteren Ausgestaltung der Erfindung werden zur Bildung eines Wirbelkörperimplantats zwei oder mehrere Scheiben zusammengesetzt. In diesem Fall wird ein Vorrat von einem Sortiment von Scheiben unterschiedlicher Höhe und Durchmesser gehalten. Für eine Implantation wird der Abstand zwischen den Wirbeln gemessen und entsprechend dicke bzw. hohe Scheiben aus dem Sortiment zusammen kombiniert, derart, daß sie in ihrer Gesamtheit die gewünschte Höhenabmessung haben. Die herausgesuchten Scheiben, sie bestehen aus Teilen gleicher Form, nur mit unterschiedlicher Höhe, werden im Baukastenprinzip aufeinandergestapelt und als fertiges Implantat zwischen die Wirbelkörper gesetzt, die dazu geringfügig auseinandergezogen werden. Auch hier ist nach dem Einsetzen des Implantats keine Regulierung oder Justierung desselben innerhalb des Patientenkörpers erforderlich.

Mit Hilfe eines Computers lassen sich die zu kombinierenden Höhen der Scheiben sekundenschnell ermitteln, so daß zwischen Wirbelabstandsvermessung bis zum Erhalt des einsetzbaren Implantats ein minimaler Zeitaufwand erforderlich ist.

Die radiale und drehsichere Verankerung der zusammengesetzten Scheiben läßt sich vielfältig bewältigen.

Gemäß einer Ausgestaltung der Erfindung weisen die Scheiben fluchtende Bohrungen auf, in die Verankerungsstifte eingesetzt werden. Bei dieser Ausgestaltung sind die Scheiben sowohl radial als auch drehsicher miteinander verbunden. Außerdem sind die Scheiben fertigungstechnisch sehr einfach herzustellen.

Eine andere Möglichkeit ist, die Scheiben direkt mit eingeformten Verankerungsmitteln, wie z.B. Nut und Feder, Stift und Bohrung, herzustellen.

Auch die Scheibenpackungen können als Ringscheiben ausgebildet werden, wobei der Hohlraum zur radialen Verankerung der Ringe mit Knochenmaterial oder -zement ausgefüllt werden kann. Vorteilhaft ist es, wenn der Innenmantel der Ringscheiben unregelmäßig ist oder geometrische Unregelmäßigkeiten aufweist. Jede Abweichung von der kreiszylindrischen Form dient zur drehsicheren Verankerung der aufgestapelten Scheiben, wenn der Hohlraum der Ringscheiben mit einem härtenden Material ausgefüllt wird.

Für den sicheren Halt des als Scheibenstapel ausgebildeten Implantats zwischen den angrenzenden Wirbelkörpern werden Endscheiben mit einer rauhen Stirnseite vorgesehen. Die Rauhigkeit kann durch eine strukturierte Oberfläche, herausragende Spitzen, Wellen und dergleichen erzeugt werden.

In jeder Ausführung ist es möglich, die Scheiben zu einer soliden Einheit miteinander zu verkleben, z.B. mit PMMA-Zement, wenn erforderlich oder zweckmäßig.

Die Scheiben werden vorzugsweise aus einem kohlenstoffaserverstärkten Kunststoff (CFK) hergestellt, wobei die Verankerungsmittel je nach Ausgestaltung des Implantats aus demselben oder einem anderen Material bestehen können. Die Herstellung des gesamten Implantats aus CFK hat den Vorteil, daß das Implantat keine Streuung von Strahlen bewirkt, so daß die Wirbelsäule und das angrenzende biologische Gewebe auch nach dem Implantieren eines Wirbelkörperersatzes mit allen bildgebenden Verfahren (CT, MR) untersucht werden kann.

Bekannte Wickeltechniken lassen sich zur serienmäßigen Fertigung der Implantat-Elemente anwenden. Die Ringscheiben können beispielsweise mittels einer Flechtmaschine, die zusätzlich mit unidirektionalen Fasern (UD) bestückt ist, hergestellt werden. Mittels eines Stabdornes, der durch das Flechtauge gezogen und mit UD-Fasern und Flechtwerk umlegt wird, wird ein Faserverbundrohr in einem Arbeitsgang hergestellt, von dem dann die Ringscheiben abgeschnitten werden. Der Stabdorn ist vorzugsweise aus dem auch als Trennmittel verwendbaren PTFE (Polytetrafluorethylen). Der Stabdorn kann dabei ein Vieleck als Querschnitt haben oder über die Länge Nuten und/oder Erhebungen aufweisen, wodurch im Faserverbundrohr bzw. in den Ringscheiben die für die drehsichere Verankerung dieerforderliche Innenmantelgeometrie direkt bei deren Herstellung gebildet wird.

Auch Wickelverfahren unter Anwendung von Fasern oder Fasergelegen erlauben fertigungstechnisch einfache und für Serienfertigung geeignete Herstellverfahren. Es können einheitliche Streben für die Einzelscheiben und die Scheibenpackungen konzipiert werden.

Die Erfindung wird anhand von in der Zeichnung schematisch dargestellten Ausführungsbeispielen näher erläutert. Es zeigen:

Figuren 1 und 2
ein erstes Ausführungsbeispiel,

Figuren 3 und 4
ein zweites Ausführungsbeispiel,

Figuren 5 bis 8
je ein weiteres Ausführungsbeispiel.

Der Erfindung liegt der Gedanke zugrunde, daß der Chirurg an Ort und Stelle direkt nach Kenntnis der tatsächlichen Abmessungen den Wirbelkörperersatz zusammenstellt, ohne die Hilfe eines Prothesentechnikers. Dazu wir ein Vorrat von Strängen unterschiedlicher Durchmesser und/oder eines Sortiments von Implantatkomponenten unterschiedlicher Durchmesser und Höhen gehalten, so daß für den jeweiligen Fall entweder eine entsprechende dicke Scheibe aus dem entsprechenden Strang herausgetrennt oder die entsprechende Anzahl von Komponenten mit entsprechenden Abmessungen herausgeholt und zusammengesetzt zu werden braucht, ohne Schraubjustier-oder andere Handgriffe vornehmen zu müssen. Die Auswahl der Scheiben nach ihrer Höhe im letzten Fall kann mittels eines Rechners erfolgen.

Die Grundlage eines zusammengesetzten Implantats besteht im Aufstapeln von vorgefertigten Scheiben, wobei diese Scheiben eine runde, mehreckige oder unregelmäßige Außenkontur haben können. Es können volle Scheiben oder auch Ringscheiben als Komponenten verwendet werden. Es werden Scheibensätze mit unterschiedlichen Durchmessern benötigt, wobei jeder Satz eines Durchmessers mit Scheiben unterschiedlicher Höhe bestückt ist. Steht der Durchmesser des einzusetzenden Implantats fest, so werden in dem entsprechenden Scheibensatz noch die entsprechenden Höhen ausgesucht, so daß nach dem Zusammensetzen der gewählten Scheiben sich die erforderliche Implantathöhe ergibt.

Um das Sortiment bezüglich der Scheibenhöhe möglichst klein zu halten, können beispielsweise wenige hohe Abmessungen vorgesehen werden, die mit niedrigen Scheiben, z.B. millimeterdicken Scheiben, entsprechend ergänzt werden.

In Fig. 1 ist ein Ausführungsbeispiel gezeigt, bei dem ein fertiges Implantat 10 aus drei dickeren Scheiben 11, einer dünnen Scheibe 12 und zwei Endscheiben 13 bzw. 14 zusammengesetzt ist.

Wie in Fig. 2 dargestellt ist, bestehen die Scheiben 11 bis 14 aus runden Ringscheiben mit einer Innenbohrung 15 und jeweils vier regelmäßig auf die Ringscheibe verteilten Bohrungen 16. In diese Bohrungen 16 werden Verankerungsstifte 17 eingeführt. Gemaß der Ausführung nach Fig. 1 sind die Stifte 17 mit ihrem jeweils einem Ende 18 mit einer Scheibe 11, 13 verbunden, während sie mit dem anderen Ende 19 in die Bohrung einer nach-

sten Scheibe 11 hineinragen. Bei dieser Ausgestaltung wird eine Endscheibe 14 ohne Stift auszugestalten sein. In gleicher Weise werden die dünnen Scheiben 12 lediglich Bohrungen 16 aufweisen.

Es ist natürlich auch möglich, die Stifte 17 als von den Scheiben 11 bis 14 getrennte Bauteile herzustellen, so daß die Stifte erst bei dem Zusammensetzen eines Implantats 10 in die Bohrungen 16 eingeführt werden.

Anstelle von Stiften als Verankerungsmittel können auch Nut- und Federsysteme in jeder möglichen Konfiguration vorgesehen werden.

In Fig. 3 ist ein Ausführungsbeispiel gezeigt, bei dem die Scheiben 21 auf der einen Stirnseite mit einer Ringfeder 22 und auf der anderen Stirnseite mit einer damit fluchtenden Ringnut 23 versehen sind. Um eine Verankerung auch in Torsionsrichtung zu erreichen, können anstelle der Ringfeder 22, wie in Fig. 4 gestrichelt angedeutet, Federsegmente 24 vorgesehen werden, die in entsprechende Nutsegmente der nächsten Scheibe eingreifen.

In den dargestellten Ausführungsbeispielen wurden runde Scheiben mit kreissymmetrisch verteilten Verankerungselementen gezeigt. Es ist selbstverständlich jede asymmetrische Anordnung der Verankerungselemente sowie jede Außenkontur der Scheiben möglich, soweit letztere mit der Kontur der Wirbelkörper im Einklang steht

Ringscheiben oder volle Scheiben lassen sich fertigungstechnisch einfach aus jedem biokompatiblen Material herstellen, da sie an keine besondere Formgebung gebunden sind. Die Form kann sogar teilweise an das Herstellungsverfahren angepaßt werden. Für die Serienfertigung gut geeignete Herstellungsmethoden sind Wickeln oder Ziehen von Faserverbundrohren, aus denen die Scheiben als Einzelelement oder für die vorstehend beschriebenen Scheibenpackungen herausgesägt, geschnitten bzw. -getrennt werden. Im Wickelverfahren können nach bekannten Methoden Fasern oder Fasermatten verwendet werden. Im Flechtverfahren wird, wie es in Fig. 5 angedeutet ist, ein entsprechend geformter Stabdorn 30, z.B. mit rechteckigem Querschnitt durch ein Fadenauge 31 durchgezogen und dabei mit Bündeln von längsgerichteten, mit Matrix imprägnierten UD-Fasern 32 sowie mit äußeren Flechtfasern 33 umgeben. Nach dem Aushärten der Matrix werden aus dem so hergestellten Faserverbundrohr Ringscheiben 35 herausgetrennt, wobei der Dorn vor oder nach der Trennung der Ringscheiben entfernt wird. Der als Faserverbundrohr ausgebildete Strang dient sowohl zur Herstellung von Einzelscheiben als auch von Scheiben für ein Scheibenpaket gemäß Fig. 1.

Einzelscheiben 35 werden bei Bedarf keilförmig (Fig. 6, $h_1 > h_2$) herausgetrennt. Im neutralen Bereich 37 können Öffnungen 38 vorgesehen werden, die zum Eingriff von Implantionswerkzeugen und Fixationsmitteln, wie Krampen 39 verwendet werden.

Der Hohlraum 36 kann mit fremdem oder dem patienteneigenen Knochenmaterial oder mit Knochenzement ausgefüllt werden, das ebenfalls durch die Öff nung 38 einführbar ist. Bei zusammengesetzten Scheiben dient der Knochenzement gleichzeitig zur Verankerung der Scheiben in radialer Richtung und aufgrund des nicht kreissymmetrischen Innenquerschnittes 36 auch in Torsionsrichtung. Anstelle des rechteckigen Innenquerschnittes kann jede andere Konfiguration außer der Kreisform zur Sicherung gegen Drehbeweglichkeit zwischen den Scheiben gewählt werden.

Fig. 7 zeigt eine Form mit einem zylindrischen Innenmantel 40, der mit einer Nut 41 und einer Erhebung 42 zur Torsionsverankerung ausgestattet ist.

Bei Bedarf werden die Scheiben oder Ringscheiben einseitig mit einer Klebstoffhülsen 44 einschließenden Starterfolie 43 versehen, wie in Fig. 7 gezeigt ist. Wenn zwei Scheiben 45 zur Bildung des Implantats aufeinandergelegt und axial gepreßt werden, platzen die Klebstoffhülsen 44 auf, so daß der Klebstoff sich zwischen den Scheiben 45 verteilt und die Scheiben miteinander verbindet. Die Klebverbindung kann als einzige Verbindung oder ergänzend zu den vorstehend genannten Verankerungsmitteln verwendet werden.

In der Ausführung nach Fig. 7 sind ferner Bohrungen 46 gezeigt, die radial durch die Ringscheibe 45 gefuhrt sind. Sie dienen zur Einführung des Knochenzements oder Knochenmaterials in den Hohlraum 47.

Die Endscheiben 13, 14 eines Implantats 10 haben an ihrem freien, die Auflage für den Wirbelknochen dienenden Stirnende eine rauhe, strukturierte oder mit diskreten Erhebungen versehene Oberfläche 20. Diese sollen in Zusammenwirkung mit den angrenzenden, gegen das Implantat 10 drückenden Wirbelkörpern 50, 51 die Verankerung innerhalb der Wirbelsäule gewährleisten und als Anwachshilfe dienen. Wie vorstehend beschrieben, kann bei Bedarfim implantierten Zustand durch eine nichtgezeigte radiale Bohrung Knochenzement oder-material 53 in die Innenbohrung 15 bis an dieangrenzenden Wirbelkörper 50, 51 gedrückt werden. Bei einem Einscheiben-Implantat werden beide Seiten entsprechend ausgestaltet. Eine rauhe Fläche läßt sich durch Verwendung einer grobkörnigen Schneidwerkzeuge direkt im Trennvorgang vom Strang bilden.

Die Implantation eines derartigen Wirbel- und/oder Bandscheibenersatzes bedingt keine systemspezifischen Schwierigkeiten. Wenn der chirurgische Schritt soweit gekommen ist, daß der Abstand zwischen den angrenzenden Wirbelkör-

pern feststellbar ist. wird mittels dieses Wertes im Rechner die Zusammensetzung der Scheibenhöhen für das Implantat errechnet, herausgesucht und zusammengesetzt oder mittels eines genau einstellbaren Werkzeugs die Scheibe vom Strang abgetrennt. Die angrenzenden Wirbelkörper werden etwas auseinandergezogen und das im Baukastensystem zusammengesetzte Implantat bzw. die Scheibe zwischengelegt. Außer dem Plazieren des Implantats sind keine weiteren Handgriffe bezüglich des Implantats notwendig. Außer der Implantathöhe variiert auch der Durchmesser des Implantats. Das Scheiben- und/oder Strangsortiment ist daher auch nach Querschnitten zu bestücken.

In Fig. 8 ist schließlich ein hohler Strang 50 unregelmäßiger Konfiguration gezeigt, der aus 1 bis 20 Flechtwerken 51 gebildet ist. Ein nicht gezeigter Dorn wird entsprechend oft durch das Ringfadenauge einer Flechtmaschine gezogen und dabei mit entsprechend vielen Flechtwerken und Matrixmaterial überzogen. Mit Trennscheiben werden an Trennlinien 52 die Scheiben 53 für ein Implantat oder Implantatelement herausgeschnitten.

Patentansprüche

1. Implantat für die Wirbelsäule, bestehend aus mindestens einem steifen Element, dadurch gekennzeichnet, daß das Implantat aus mindestens einer Scheibe (11 bis 14, 21, 35, 45, 53) besteht, die direkt zwischen zwei angrenzenden Wirbelkörpern zwischenlegbar ist und je nach Wirbellage parallele oder zueinander im Winkel stehende Auflageflächen hat.

2. Implantat nach Anspruch 1, dadurch gekennzeichnet, daß die Scheibe als Ringscheibe (35, 45, 53) mit regelmäßigem oder unregelmäßigem Umfang ausgebildet ist, und daß der Innenumfang der Scheibe einen vieleckigen oder unregelmäßigen Querschnitt hat.

3. Implantat nach Anspruch 1 oder 2, dadurch gekennzeichnet, daß die Auflageflächen der Scheibe (14, 35, 53) Rauhigkeiten, Porenwelligkeiten oder andere Unebenheiten aufweisen.

4. Implantat nach Anspruch 1, dadurch gekennzeichnet, daß die Auflageflächen der Scheiben (14, 35, 53) herausragende Spitzen (20) aufweisen.

5. Implantat nach einem der vorhergehenden Ansprüche, dadurch gekennzeichnet, daß die Scheibe (45) Kanäle (46) aufweist, in die Knochenzement oder Knochenmaterial einbringbar ist.

6. Implantat nach einem der vorhergehenden Ansprüche, dadurch gekennzeichnet, daß die Scheibe (11 bis 14, 2135, 45, 53) aus faserverstärktem Kunststoff besteht und im Wickelverfahren oder ausaufgerollten Fasermatten hergestellt ist.

7. Implantat nach einem der vorhergehenden Ansprüche, dadurch gekennzeichnet, daß die Scheibe (53) aus einem Strang (32, 33 bzw. 50) geschnitten ist.

8. Implantat nach Anspruch 7, dadurch gekennzeichnet, daß der Strang (32, 33 bzw. 50) aus unidirektionalen Fasern (32) und/oder Flechtlagen (33, 51) besteht.

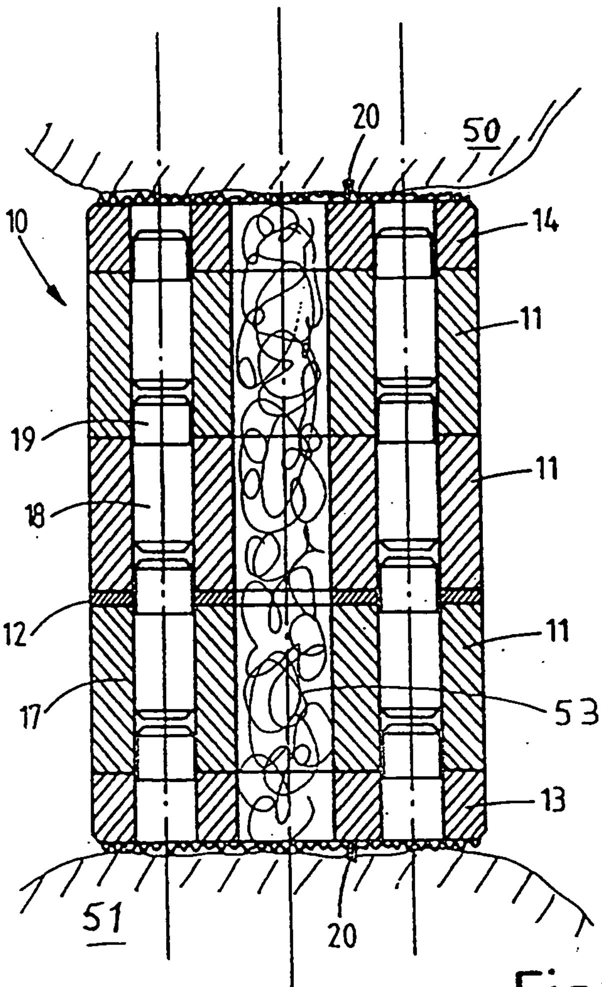

Fig. 1

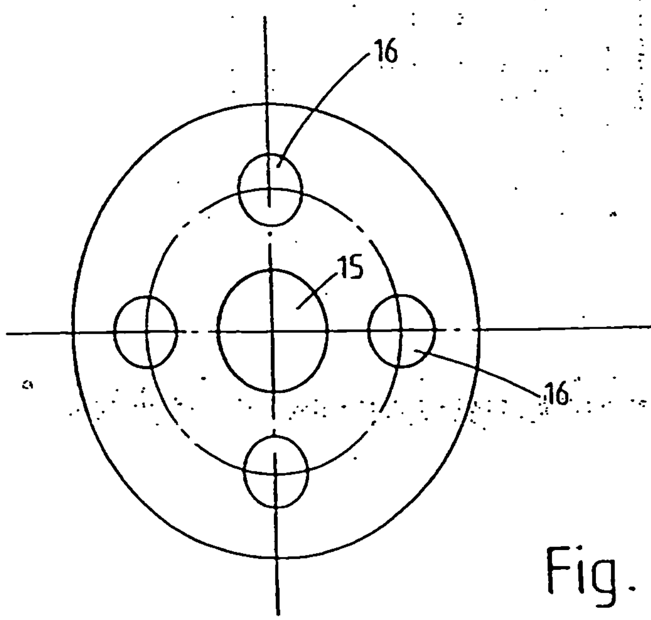

Fig. 2

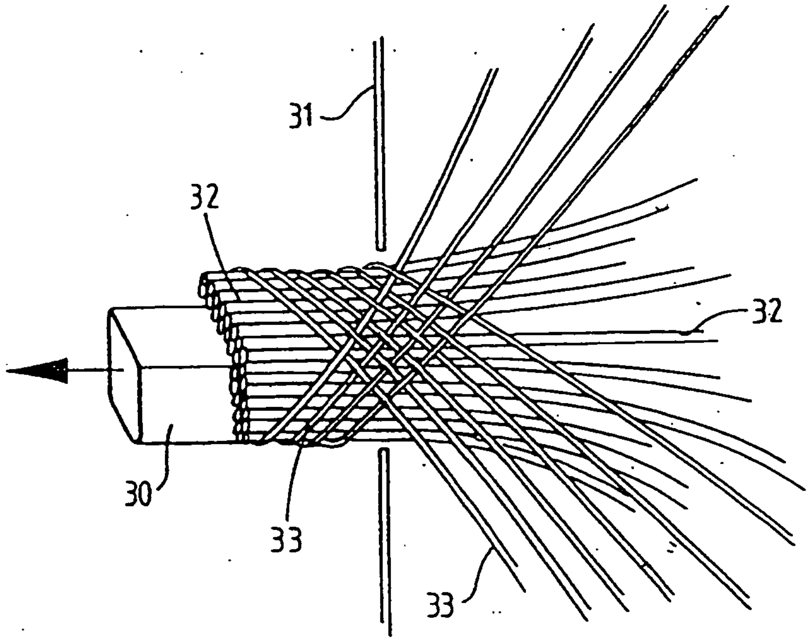

Fig. 5

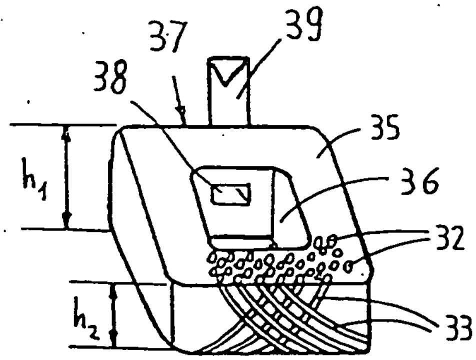

Fig. 6

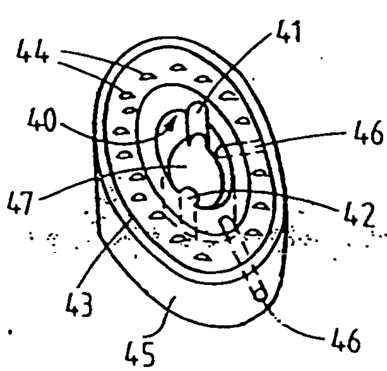

Fig. 7

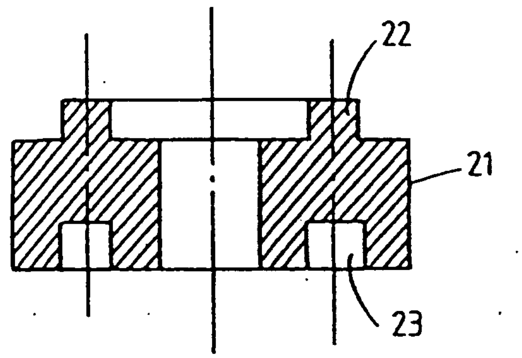

Fig.3

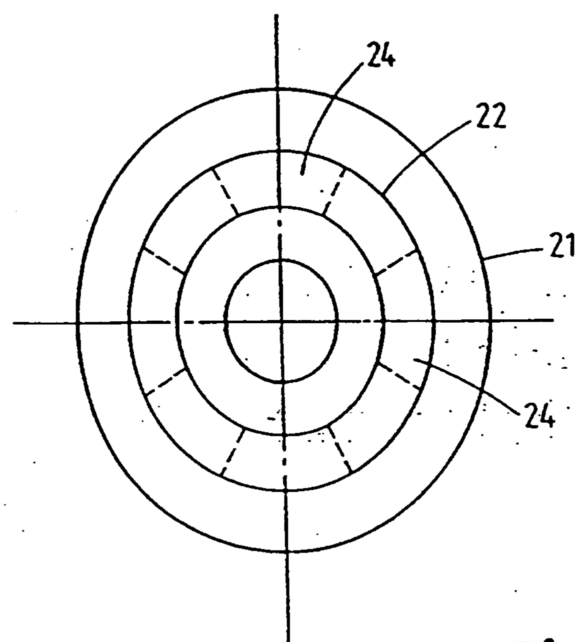

Fig.4

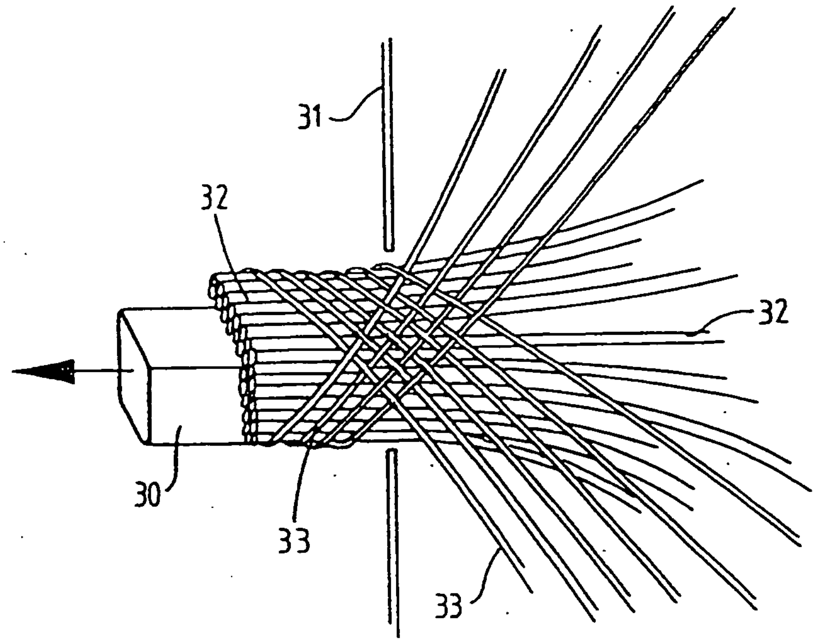

Fig. 5

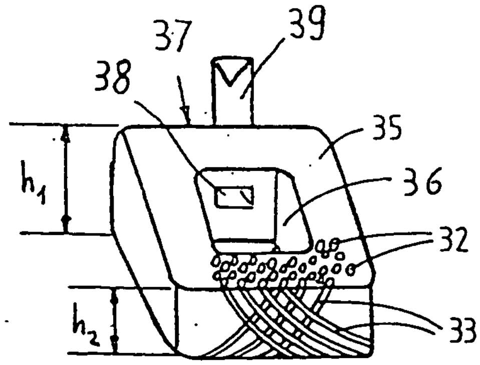

Fig. 6

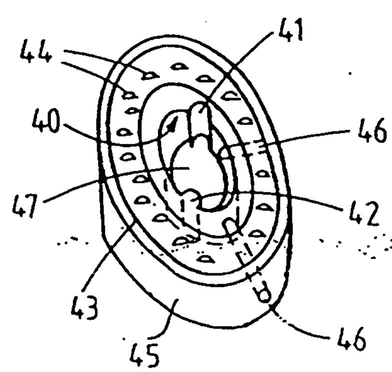

Fig. 7

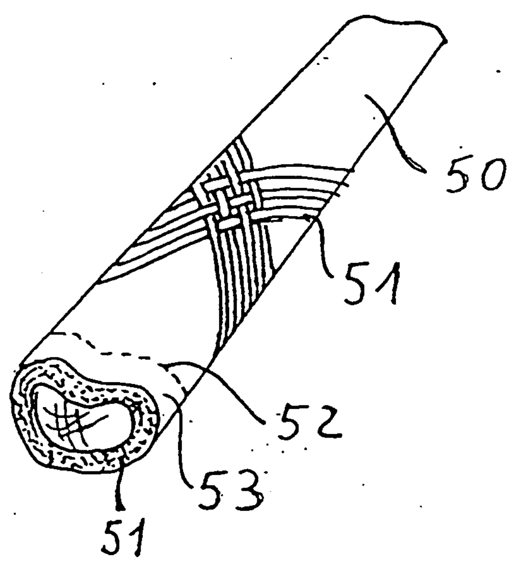

Fig.8

Attachment A

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European Patent Office

EUROPEAN PATENT APPLICATION
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Date the unexamined patent application, on which no grant has taken place on or before the said date, has been made available to the public by printing or a similar process: December 9, 1992 in 'Patentblatt' 92/50
Designated high contracting parties to regional patent conventions: CH DE FR GB IT LI
Applicant; MAN Ceramics GmbH
Inventor: Wolfgang Siebels, Spitzwegstraße 17, D-8360 Deggendorf and Rudolf Ascherl, Türkenstraße 53, D-8000 Munich

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[Title in German of the object of the invention:]
Wirbelkörperimplantat

INTRAVERTEBRAL BODY IMPLANT

The invention pertains to an intravertebral (intraspinal) body implant for vertebral (spinal) columns consisting of at least a rigid element.

Intravertebral bodies have different size along a spinal column, and vary from patient to patient. Therefore, when an

intravertebral body is substituted by an implant, it is necessary that the implant is matched to the effective size of the interval between the adjacent intravertebral bodies.

In order for an allowance to be made for this interval, implants were developed (DE 30 23 942 C3), which essentially consist of two parts, which are connected to one another by means of a threaded connection, and whose axial height can be changed by rotation, or which can be matched to the interval between the intravertebral bodies. By means of transverse bolts or other means of anchoring, the two parts are anchored in a way, which is resistant to torsional stress or prevents a rotation. Therewith, by means of a single embodiment an entire range of intervals can indeed be covered, however the adjustment in height takes relatively much time in the case of a fine thread.

An implant of the generic kind, which rectifies this imperfection, is known from the WO 90/00037, which implant is inserted solely between two vertebrae by means of a tool. However, the approximately rectangular implant is assembled out of intricate individual parts.

Therefore, the objective to develop an implant of the kind mentioned at the outset, which can rapidly be implanted and which - from the standpoint of manufacturing engineering - can also easily be manufactured for a multiplicity of overall dimensions, forms the basis of the [proposed] invention.

In accordance with the invention, the set objective is

achieved with the help of the features, cited in claim 1.

Not only is a disk easily inserted into a spinal gap but it can also be manufactured in such a way that it can very easily and dimensional correct be matched to a certain case of application. For example, in the case of a specific application, it is thus possible that first of all the disk is cut out of a prefabricated solid or hollow strand, sterilized, or separated in sterile state with the help of a sterile grinding tool and sterile water. By using a coarse-grained grinding, respectively cutting tool, a rough surface, promoting the growth process, is imparted to the sectional areas of the implant [spinal] disk, which form the support for the intravertebral bodies.

Basically, the use of a disk of any configuration, be it of round, polygonal, irregular contour, is possible. Also, the inner contour of an annular disk can be created as occasion demands.

The contact surface of a disk, which is being used for the adjacent intravertebral bodies, is designed as structured for the promotion of the growth process, and is selected as being coarse, or running in different directions. Anchoring means in the form of projecting tips or spikes are used for the immediate securing of the prosthesis after the implantation takes place.

The disk-shaped implant is preferably made of fiber-reinforced plastic [FRP]. In accordance with a preferred embodiment of the invention, in order to produce a single-piece implant, the disk is cut out of a hollow strand, which consists

of a multiple number of braiding layers [plaiting layers]. The braiding layers, are wound up one after another on a correspondingly shaped mandrel [arbor], preferably on a mandrel, having rectangular cross-section and rounded corners, directly in a braiding machine. The disks are cut off with the desired height, which can vary over the disk. Implants of this kind are characterized in that they can be manufactured in an extraordinarily easy way, in which the fiber orientation equally imparts an optimal rigidity and strength to the implant.

In accordance with yet another embodiment of the invention, two or more disks are assembled, in order for an intravertebral body implant to be produced. In that case, a stock of an assortment of disks, having different height and diameter, is kept, available at hand. For the purposes of an implantation, the interval between the vertebrae is measured, and correspondingly thick, respectively high, disk of the assortment are combined together in such a way, that they have the desired vertical dimension in their entirety. The selected disks - they consist of parts of analogous shape, only having different height - are stacked one above another, in accordance with the modular principle, and are inserted as ready-made implant between the intravertebral bodies, which - to this end- are slightly pulled apart. Also, in this case, after the insertion of the implant, a regulation or adjustment of the latter inside the patient body is not required.

With the help of a computer, the disks' heights, which are to be combined, are instantaneously determined so that a minimal time input is required between the spinal interval measurement and the reception of the insertable implant. The radial anchoring, and the anchoring, preventing a rotation and resisting the torsional stress, of the assembled disks, can be mastered in a multifarious way.

In accordance with an embodiment of the invention, the disks have aligned boreholes, into which anchoring pins or studs can be inserted. In that embodiment, the disks are radially connected to one another, and also in such a way that they resist the torsional stress [i.e. possess torsional strength], and cannot rotate. Moreover, from a manufacturing engineering standpoint, the manufacturing of the disks is very easy.

Another possibility consists in that the disks are directly produced as having molded anchoring means, such as, e.g., groove and tongue, pin [stud] and boreholes.

Also, the disk packages can be designed as annular disks whereby the hollow space is filled with bone material or bone cement for the purposes of a radial anchoring of the rings. It is advantageous when the inner jacket of the annular disks is irregular, or has geometrical irregularities. Each deviation from the circular cylindrical shape is used for a torsionally resistant anchoring of the stacked disks when the hollow space of the annular disks is filled up with a hardening material. In

order for a reliable support of the implant - which is designed as a disk stack - to be achieved between adjacent intravertebral bodies, end-disks are provided, having a rough frontal side. The roughness can be generated by means of a structured area, projecting tips, undulations, and similar.

In each embodiment, it is possible to glue the disks with one another into a solid unit, e.g., with the help of PMMA* cement, if required,or if functionally feasible. [*Translator's note: PMMA = polymethyl methacrylate].

Preferably, the disks are made of a carbon-fiber reinforced plastic (CFP) whereby the anchoring means - according to the design of the implant - can consist of the same, or another material. The manufacturing of the entire implant of CFP has the advantage that the implant does not bring about any scattering of rays, so that the spinal column and the adjacent biological tissue can also be examined after the implantation of a spinal-column replacement with the help of all image-producing methods (CT*, MR*) [*Translator's note: CT = charge-transfer (absorption band or electron-transfer band); MR = magnetic resonance).

Known winding techniques may be used for series-manufacturing of the implant elements. For example, the annular disks ["washers"] can be made with the help of a braiding machine, which is additionally outfitted with unidirectional fibers (UD). By means of bar-shaped mandrel, which is pulled

through the braid eyelet, around which there are laid UD-fibers and braiding, a bonded-fiber tube is generated in a single run, from which the annular disks are afterwards cut off. The bar-shaped mandrel is preferably of PTFE (polytetrafluoroethylene), which is also used as mold release agent. At the same time, the bar-shaped mandrel can have a polygonal cross-sectional area, or grooves all over the length, and/or elevations, as a result of which the inner-jacket geometry, required for the torsionally-resistant anchoring, can directly be formed in the bonded-fiber tubes, respectively in the annular disks, over the course of their manufacturing.

Also, winding methods using fibers or fiber-woven fabrics allow a manufacturing process, which is simple from the standpoint of manufacturing engineering, and suitable for series-manufacturing. Unified struts for the individual disks and the disk packages [packings] can be designed.

The invention is elucidated in greater detail by means of exemplified embodiments, diagrammatically represented in the drawing, wherein

Figs. 1 and 2 show a first exemplified embodiment,

Figs. 3 and 4 show a second exemplified embodiment

Figs 5 thru 8 show another exemplified embodiment, each.

The notion that the surgeon directly assembles the spinal body substitute [replacement set] on the very spot by knowing the actual overall dimensions and without the help of a prosthesis

technician, forms the basis of the invention. To this end, a stock of strands, having different diameter and/or a supply of an assortment of spare implant components, having different diameter and height, is maintained so that for each relevant case either a corresponding thick disk needs to be separated from the relevant strand, or the relevant number of components, having relevant dimensions ought to be taken out, and assembled without threaded [screw] adjustments or other types of handling. In the last case, the selection of the disks according to their height can take place by means of a computer.

The base of an assembled implant consists in the stacking of prefabricated disks whereby these disks can have a round, polygonal or irregular outer contour. Solid disks or also annular disks can be used in their capacity as components. Disk assortment sets, having different diameters, are necessary whereby each assortment of a diameter is outfitted with disks, having different diameter. If one is absolutely certain about the diameter of the disk to be used, the corresponding heights are yet to be selected within the framework of the corresponding disk batch [assortment set] so that after the selected disks are assembled, the required implant height is thus produced.

For example, in order for the assortment with respect to the disk height to be maintained as small as possible, few high dimensions can be provided, which are correspondingly supplemented with lower disks, e.g., having a thickness of

several millimeters.

Fig.1 shows an exemplified embodiment, in which a ready-made implant 10 is assembled out of three thicker disks 11, a thin disk 12, and two end-disks 13 and 14.

As diagrammatically represented in Fig. 2, the disks, 11 thru 14, consist of round annular disks, having an inner borehole 15, and four boreholes 16, respectively, which are equitably distributed over the annular disk. Anchoring pins [studs] 17 are introduced into these boreholes 16. In accordance with the embodiment, depicted in Fig. 1, the pins 17 are connected with one of their respective ends 18 to a disk 11, 13 while they protrude with the other end 19 into the borehole of the subsequent disk 11. In this embodiment, an end-disk 14 is designed without pin [stud]. In an analogous way, the thin disks 12 have solely boreholes 16.

Self-evidently, it is also possible to produce the pins as structural components separated from the disks 11 thru 14 so that the pins are introduced into the boreholes 16 only when the assembly of an implant 10 takes place.

Instead of pins, groove-and-tongue systems can also be provided as anchoring means in each possible configuration.

Fig. 3 shows an exemplified embodiment, in which the disks 21 are provided with an annular [ring] spring 22 on one of the frontal sides whereas, on the other frontal side, they are provided with an annular groove 23, aligned with the annular

spring 22. In order for an anchoring to be also achieved in the torsional direction, spring segments 24 can be provided instead of the annular [ring] springs 22, as indicated by the dotted line in Fig. 4, which spring segments engage into corresponding grooved segments of the next disk.

In the diagrammatically represented exemplified embodiments, there were shown round disks, having a circularly symmetric distribution of the anchoring elements. It is self-evident that any asymmetric arrangement of the anchoring elements as well as of any outer contour of the disks is possible as long as the latter are in agreement with the contour of the intravertebral bodies.

From the standpoint of manufacturing engineering, annular disks or solid disks can easily be manufactured of any biologically compatible material because they are not bound to a particular shaping. The shape can even partially be matched to the manufacturing method. Manufacturing methods, which are adequate for the series-manufacturing are winding or pulling of bonded-fiber tubes, out of which the disks are sawn off, cut off, or separated, either as individual element or as elements for the disk packings [packages], described above. In the winding method, fibers or fibrous mats are used in accordance with known methods. In the braiding method, as depicted in Fig. 5, a correspondingly shaped bar-shaped mandrel 30, e.g., having a rectangular cross-section, is passed through a thread eyelet [guide] 31, and, in

doing so, it is surrounded with bundles of longitudinally directed, unidirectional [UD] fibers 32, impregnated with matrix, as well as with outer braiding fibers 32. After the solidification of the matrix, annular disks 35 are separated out of the bonded-fiber tube thus produced, whereby the mandrel is removed prior to or after the separation of the annular disks. The strand, which is designed as bonded-fiber tube, is used for the manufacturing of individual disks as well as for the manufacturing of a disk package, as depicted in Fig. 1.

When needed, individual disks 35 are separated as wedge-shaped ones (Fig. 6, ($h_1 > h_2$). In the neutral area 37. there can be provided openings 38, which are used to engage the implantation tools and fixation means, such as staples [cramp irons; clams; or clips] 39.

The hollow space 36 can be filled up with extraneous bone material, or with patient's own bone material, or with bone cement, which can also be introduced through the opening 38. When the disks are assembled, the bone cement is also used for the anchoring of the disks in the radial direction, and - due to the non-circular symmetric inner cross-section 36 - in the torsional direction as well. Instead of the rectangular inner cross-section, any other configuration - save the circular shape - can be selected, in order for a free rotational motion between the disks to be precluded.

Fig. 7 shows a shape, having a cylindrical inner jacket 40, which is outfitted with an elevation 42 for torsional anchoring.

If need arises, the disks or annular disks are provided with a starter foil 43- as shown in Fig 7 - surrounding adhesive cartridges 44. When two disks 45 for the formation of the implant are placed one above another, and axially compressed, the adhesive cartridges 44 burst open, so that the adhesive is distributed between the disks 45, and connects the disks with one another. The adhesive connection can be used as single connection or supplementarily to the aforementioned anchoring means.

In the embodiment in accordance with Fig. 7, there are shown additional boreholes 46, which are radially guided through the annular disk 45. They are used for the introduction of the bone cement or bone material into the hollow space 47.

On their free frontal end, used as the support for the spinal bones, the end-disks 13, 14 of an implant 10 have a surface 20, which is rough, structured, or provided with discrete elevations. In interaction with the adjacent intravertebral bodies 50, 51, which are pressing against the implant 10, the said elevations should guarantee the anchoring inside the spinal column, and be used as growth help. As described above, bone cement or material 53 can be pressed - if need arises - through a non-diagrammatically represented radial borehole into the inner borehole 15 up to the adjacent intravertebral body 50, 51. In the case of a single-disk implant, both sides are correspondingly

designed. A rough surface can be directly formed within the framework of the separation process from strand by using a coarse-grained cutting tool.

The implantation of an intervertebral disk substitute and/or an intravertebral fibrocartilage [intravertebral ligament; intervertebral cartilage] of this kind is not subject to any system-specific problems. If the surgical step has gone so far that the interval between the adjacent vertebral bodies can be adjusted, the assembly of the disk-heights for the implant is calculated in the computer with the help of this value, selected, and assembled, or with the help of a precisely adjustable tool, the disk is separated from the strand. The adjacent vertebral bodies are somewhat pulled apart, and the implant, respectively the disk, assembled within the framework of the modular method, is inserted. As far as the implant is concerned, no additional manipulation procedures or handling are necessary save for the placement of the implant. Besides the implant height, the diameter of the implant also varies. Hence, the disk and/or strand assortment is also to be supplied according to cross-sectional areas.

Finally, in Fig. 8, there is shown a hollow strand 50, having an irregular configuration, which hollow strand is formed out of 1 to 20 braidings 51. A mandrel, which is not diagrammatically represented, is often pulled through the annular thread eyelet of a braiding machine, and, in doing so, lined with

many braidings and matrix material, respectively. With the help of separating disks, the disks 53 for an implant or implant element, are cut out at separating lines 52.

Patent Claims

1. Implant for spinal columns, consisting of at least a rigid element, characterized in that the implant consists of at least a disk (11 thru 14, 21, 35, 45, 53), which can be directly inserted between two adjacent vertebral [intravertebral] bodies, and according to the spinal position has parallel contact surfaces [support surfaces] or contact surfaces, which are at an angle with respect to one another.

2. Implant as claimed in claim 1, characterized in that the disk is designed as annular disk (35, 45, 53), having regular or irregular circumference, and that the inner circumference of the disk has a polygonal or irregular cross-section.

3. Implant as claimed in claim 1 or 2, characterized in that the contact surfaces of the disks (14, 25, 53) have roughness, pore undulations, or other unevennesses.

4. Implant as claimed in claim 1, characterized in that the contact surfaces of the disks (14, 35, 53) have protruding tips or spikes (20).

5. Implant as claimed in one of the preceding claims, characterized in that the disk (45) has channels (46) into which bone cement or bone material can be introduced.

6. Implant as claimed in one of the preceding claims, characterized in that the disks (11 thru 14, 21, 35, 45, 53) consist of fiber-reinforced plastic, and are made within the framework of the winding method or of wound up [batched up] fiber mats [fiber webs].

7. Implant as claimed in one of the preceding claims, characterized in that the disk (53) is cut out of a strand (32, 33, resp. 50).

8. Implant as claimed in claim 7, characterized in that the strand [hank; rope] (32, 33 or 50) consists of unidirectional fibers (32 and/or braiding layers (31, 51).

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The USPTO Translator (GERMAN & Germanic languages)
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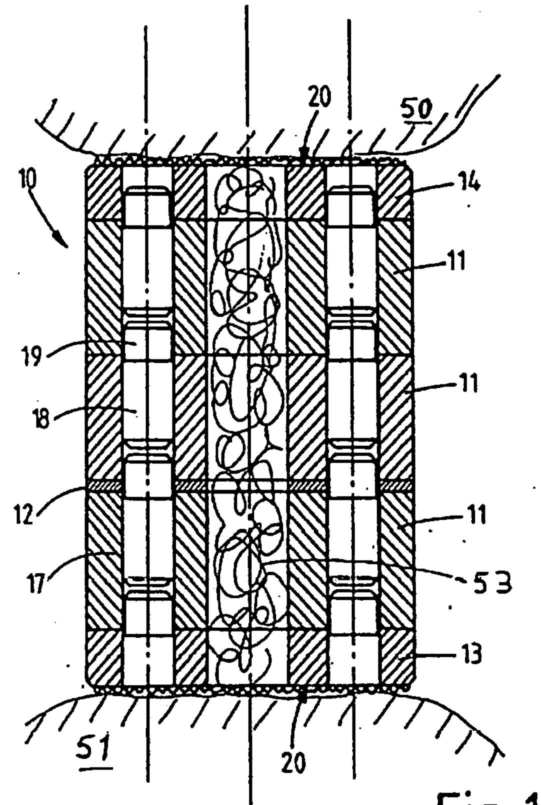

Fig.1

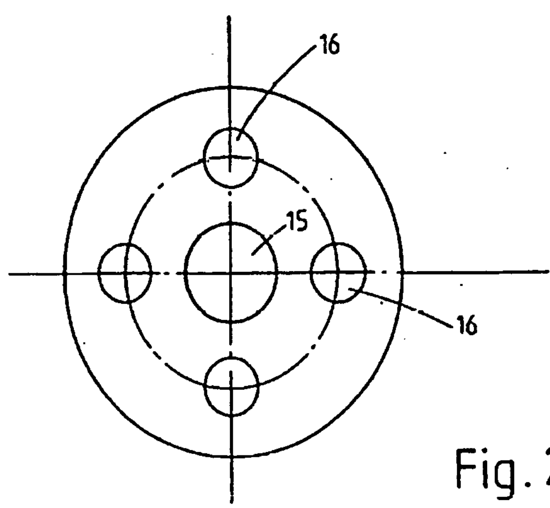

Fig. 2

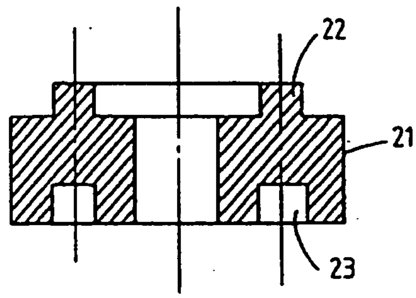

Fig. 3

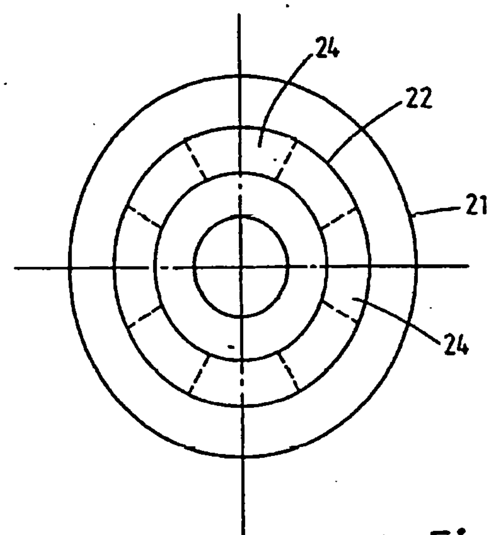

Fig. 4

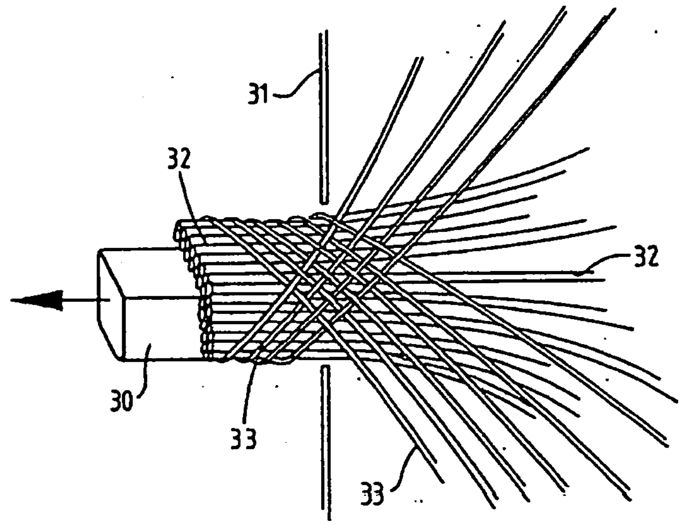

Fig. 5

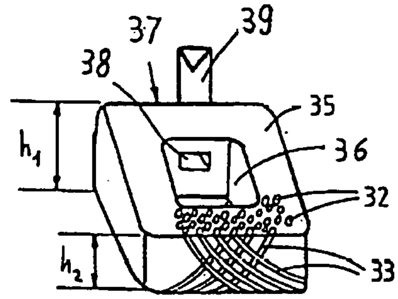

Fig. 6

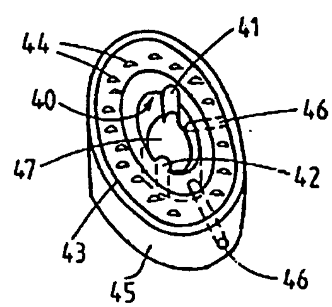

Fig. 7

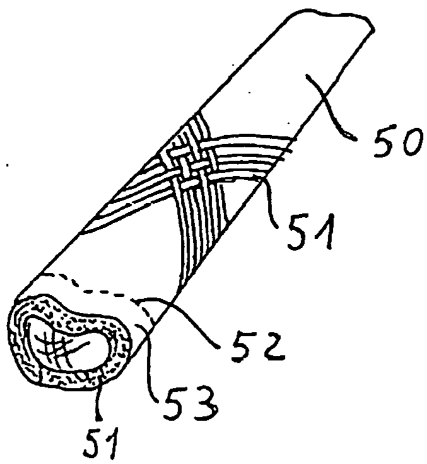

Fig.8

ATTORNEY DOCKET NO. TB 104IA CA/ 1915/13971US04

IN THE UNITED STATES
PATENT AND TRADEMARK OFFICE

Applicants:
Grooms, James, *et al.*

U.S. Serial No.: 09/905,683

Filed: July 13, 2001

For: "MULTI-COMPONENT CORTICAL BONE ASSEMBLED IMPLANT" (AS AMENDED)

Group Art Unit: 3738

Examiner: Bruce Edward Snow

CERTIFICATE OF MAILING

I hereby certify that this paper (and all papers referred to herein) is being deposited with the United States Postal Service as first class mail, postage prepaid, in an envelope addressed to: Mail Stop Amendment, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on:

April 13, 2005

Donald J. Pochopien
Registration No. 32,167
Attorney for Applicants

AMENDMENT AND RESPONSE UNDER 37 C.F.R. 1.111

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

In response to the Official Action of 12/15/04, for which a Response was due 03/15/05, now extended one (1) month to 04/15/05, the Applicants hereby request the entry of the following amendments before consideration of the arguments on the merits.

Amendments to the claims:	pages 2-4
Remarks:	pages 5-20

Amendment to the Claims:

Please substitute the following listing of the claims for any prior set of claims

Claims 1-110 (Cancelled)

111. (currently amended) An assembled bone implant suitable for implantation into a patient comprising:

a first cortical bone portion;

a second cortical bone portion;

said first cortical bone portion and said second cortical bone portion having one or more through holes sized and positioned for receiving one or more retention pins for connecting said first cortical bone portion to said second cortical bone portion; and

one or more retention pins of appropriate diameter for connecting said first cortical bone portion to said second cortical bone portion to form said assembled bone implant as a unitary body.

112. (Previously presented) The assembled bone implant of claim 113, wherein said first cortical bone portion and said second cortical bone portion each have a D shape.

113. (Previously presented) The assembled bone implant of claim 111, wherein said first cortical bone portion is stacked over said second cortical bone portion.

114. (Previously presented) The assembled implant of claim 112, wherein said retention pin is selected from the group consisting of cortical bone, a bioabsorbable synthetic polymer and titanium.

115. (Previously presented) The assembled implant of claim 114, wherein said retention pin is cortical bone.

116. (Previously presented) The assembled implant of claim 111, wherein said first cortical bone portion is a mirror image of said second cortical bone portion.

117. (Currently amended) The assembled implant of claim 112, wherein the ~~graft~~ implant has a beveled edge of defined radius.

118. (Previously presented) The assembled implant of claim 111, wherein said first cortical bone portion and said second cortical bone portion are in a stacked position relative to one another.

119. (Withdrawn) The assembled implant of claim 116, wherein said first cortical bone portion and said second cortical bone portion are in a side-by-side position.

120. (Previously presented) The assembled implant of claim 112, wherein said first cortical bone portion and said second cortical bone portion are allograft bone.

121. (Previously presented) The assembled implant of claim 112, sized and shaped in the form of a cervical implant.

122. (Previously presented) The assembled implant of claim 112, having a height between 7 and 14 mm.

123. (Previously presented) The assembled implant of claim 111, wherein said one or more retention pins comprise a cancellous bone portion.

124. (Previously presented) The assembled implant of claim 123, wherein said cancellous bone portion is treated with a bone morphogenetic protein (BMP).

125. (Previously presented) The assembled implant of claim 112, wherein said

implant has two opposing surfaces that are inscribed with teeth.

126. (Previously presented) A D-shaped assembled bone implant for implantation into a patient comprising:

a first cortical bone portion having a D shape; and

a second cortical bone portion having a D-shape;

said first cortical bone portion and said second cortical bone portion being superimposed to form D-shaped implant having the combined thickness of said first cortical bone portion and said second cortical bone portion, said D-shaped implant having a through-hole sized and positioned for receiving a retention pin for retaining said first cortical bone portion to said second cortical bone portion in stacked formation.

127. (Previously presented) The assembled implant of claim 126, wherein said retention pin is a cortical bone pin.

128. (Previously presented) The assembled implant of claim 126, wherein said retention pin is a cancellous bone portion is treated with a bone morphogenetic protein.

REMARKS

The amendments to the claims do not add new matter. Claim 111 has been amended to recite that the "assembled implant is "suitable for implantation into a patient." Support for the "assembled implant" being "suitable for implantation into a patient" is found throughout the specification, including at page 4 line 19 (". . .shipment to physicians for use in implantation procedures."). Accordingly, this amendment to claim 111 would not add new matter.

The amendment to claim 117, changes the term "graft" for which there was no antecedent support in the claim, to "implant" for which there is antecedent support in the claim. Accordingly, this amendment to claim 117 would not add new matter.

For all these reasons, the two amendments to the claims do not add new matter.

Summary of the Bases for Rejection/Objection

Claims 111-118 and 120-128 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting over all claims in USSN 10/375,540.

Claim 117 is rejected under 35 U.S.C. § 112, second paragraph, for indefiniteness.

Claims 111-118, 120-123 and 126-127 are rejected under 35 U.S.C. § 102(b) over Albee, Scientific American, "Bone Surgery with Machine Tools," 154(4) 178-181 (1936).

Claims 111-118 and 120-128 are rejected under 35 U.S.C. § 103(a) over U.S. Pat. 5,989,289 (Coates) in view of EP 517030 (Siebels).

Claims 111-118 and 120-128 are rejected under 35 U.S.C. § 103(a) over U.S. Pat. 5,192,327 (Brantigan) in view of U.S. Pat. 5,989,289 (Coates).

The Applicants will answer each of these bases for objection in Sections I-V, respectively which follow.

I. Obviousness-type Double Patenting

Claims 111-118 and 120-128 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting over all claims in co-pending sister application USSN 10/375,540. No claims have been deemed allowable in the present application or in co-pending sister application USSN 09/722,205. The Applicants will address the issue when it becomes ripe as when one or more claims become allowable in either application.

II. 35 U.S.C. § 112, Second Paragraph

Claim 117 is rejected under 35 U.S.C. § 112, second paragraph, for indefiniteness. According to the Patent Office, the term "graft," as used in claim 117, lacks an antecedent basis. In response, the Applicants have amended claim 117, by deleting the word "graft" and substituting therefor the word "implant" for which there is an antecedent basis. Accordingly, this basis for rejection has been rendered moot.

III. 35 U.S.C. § 102(b) over Albee

Claims 111-118, 120-123 and 126-127 are rejected under 35 U.S.C. § 102(b) over Albee, Scientific American, "Bone Surgery with Machine Tools," 154(4) 178-181 (1936). Citing to "all figures, specifically figures 10-12 and 15," the Patent Office states that Albee discloses the elements of claim 111:

> a first cortical bone portion;
> a second cortical bone portion;
> said first cortical bone portion and said second cortical bone portion having one or more through holes sized and positioned for receiving one or more retention pins for connecting said first cortical bone portion to said second cortical bone portion; and
> one or more retention pins of appropriate diameter for connecting said first cortical bone portion to said second cortical bone portion to form said assembled bone implant as a unitary body.

[Claim 111.]

The Applicants respectfully disagree.

Albee only has Figures 1-6. However, when the Patent Office is referring to FIGS. 10-12 and 15 of Albee, it is believed that the Patent Office is referring to the subparts in Figure 3 of Albee, which has subparts 1-15 therein. If the Applicants are wrong, then the Applicants request a corrected Official Action wherein the Figures are properly designated and the Applicants are not required to speculate.

1. Albee Does Not Disclose Implants That Exist in Assembled Form Outside the Body

As an initial matter, Applicants point out that the applicants are claiming an "assembled" implant that exists in "**assembled**" form outside the body (***in vitro***) and that is "suitable for implantation in the patient's body." They are "off the shelf" assembled devices (i.e., devices in the mechanical sense). In marked contrast, any of the grafts disclosed in Figure 3 of Albee exist only in their disclosed form inside the body (**in vivo**). There is no "assembled" implant disclosed in Albee that exists outside the body. Rather, Albee discloses shaping a **single** piece of the patient's own (autograft) bone to fit between two opposing segments of the patient's living **in vivo** bone to bridge a size gap or hold the two opposing living segments in appropriate juxtaposition. The resulting assembled structure is not an "assembled implant" it is a reconstructed area. Moreover, whatever is assembled in a patient in Albee exists only *in vivo*, and is not "suitable for implantation in a patient" because it would require removing the patients' own bones and the interconnecting piece so that they exist *in vitro* so as an assembled implant. Thus, at no time does Albee ever teach an "assembled implant" suitable for implantation in the body. Consistent with this interpretation, the Applicants have expanded the preamble of independent claim 111 to recite that the already "assembled implant" is "suitable for implantation in a patient."

Throughout Albee's disclosure, Albee discloses that the **single** piece of

bone is removed from one portion of the patient as **living** tissue, is shaped and then transferred as a **single** (living) piece to the living bone in the body of the patient:

> The **graft lives** if it is supplied sufficiently early and in quantity with blood from the host.
>
> [Albee at page 180, col. 1; emphasis added in bold.]
>
> * * *
>
> The **vascular channel**, especially the **capillaries**, in the **graft** and host bone unite.
>
> [Albee at page 180, col. 3; emphasis added in bold.]
>
> * * *
>
> Compression may kill **bone cells**, either **in graft** or host tissues, or close blood vessels that should otherwise bring nourishment **to the living graft cells.**
>
> [Albee at page 181, col.2; emphasis added in bold.]
>
> * * *
>
> The successful **living bone-graft** is based upon a tripod of exacting conditions and environment as to mechanics, physiology and biology.
>
> [Albee at page 181, col.2; emphasis added in bold.]

Thus, at no time does Albee disclose an isolated "assembled implant" that is suitable for implantation in a patient. Further, drawing 7 in Figure 3 of Albee is the only drawing that discloses the use of more than one isolated piece of bone. It shows the use of two pieces of bone that would be connected in the living body sequentially and never as "an assembled implant." For these reasons also, Albee would not be anticipatory of claim 111 or any of its dependents.

2. Half of the Items disclosed in Figure 3 of Albee are a cabinet maker's "joinery" which Albee presents for "analogy"

Addressing the merits of the rejection, in Figure 3 of Albee, each of subparts 1a, 2b, 3a, 4a, 5a, 6a, 7a, 7b, 8a, 9a, 10a 11a, 11b, 12a, 13a, and 15 are cabinetry joints (*i.e.*, "**joinery** elements"), which Albee cites to as analogy, and not actual implants in a patient:

> The fine **joinery element** in bone surgery-a group of self evident **analogies.**
>
> [Albee at caption to Figure 3; emphasis added in bold.]
>
> * * *
>
> For help with the mechanical problem, **one must go to the joiner** and **study** his various forms of **mortise** and how he selects each according to the mechanical demands of the situation (Figure 3).
>
> [Albee at page 180, col. 2; emphasis added in bold.]

In Figure 3, only subparts 1, 2, 2a, 3, 4, 5, 6, 8, 9, 10, 11, 12, 13, and 14 show a bone repair using a **single** isolated and shaped piece of living bone to connect or bridge the gap between adjacent pieces of bone *in vivo*. As discussed above, subpart 7 of Figure 3 discloses the use of two separate pieces of bone that are connected (by the disclosed mortise and tenon joint) only when attached to the body (*in vivo*). Thus, at no time does Albee teach or suggest an "assembled implant suitable for implantation in a patient."

In the Official Action, the Patent Office specifically relies upon Figures 10-12 and 15 (i.e., subparts 10-12 and 15 of Figure 3). [official Action at page 3.] However, the drawing in subpart 10, is merely a fractured femur having the ball (head) of the femur connected to the shaft by a living dowel. Again, it should be remembered that the femur so reconnected exists only *in vivo* and does not teach or suggest a stand alone assembled implant. In fact, Albee teaches against it by stating that the graft tissue **must be living.**

Regarding subparts 11 and 12 of Figure 3, the Patent office contends that "Albee teaches **superimposed** first and second cortical bone portions **each hav[ing] a D-**

shape having a through hole which receives the I shaped pin interpreted as having an appropriate **diameter**." [Official Action at page 3: emphasis added in bold.] As an initial matter, the planar-faced dovetail of subpart 11 and the planar I-shaped connector of subpart 12 do not have "diameters." One skilled in the art understands that by definition a "diameter" is only relevant to objects having a circular cross-section:

> diameter- the straight line passing through the center of a circle, sphere, etc., from one side to the other. 2. the length of such a line; width or thickness of a circular or somewhat circular, figure or object.
>
> [Exhibit B: Webster's New World Dictionary, Second College Edition, Ed, Guralnik, Prentice Hall Press, Cleveland Ohio 1986 at page 389.]

Thus, on their face, subparts 11 and 12 of Figure 3 of Albee are not anticipatory. Further, the alleged "superimposed" D-shaped bone portions of subparts 11 and 12, do **not each have a "D" shape**. Each standing alone is "C"-shaped because there is no closed surface encompassing a central through hole. Moreover, because there is no closed surface, there is no "through hole." Rather, each "C" has a slot. Further, the two allegedly "D" shaped bone portions are **not superimposed** or stacked as that phrase is used in the Applicants invention. At best, they are in a side-by-side position. However, the Patent Office has withdrawn claim 19 from consideration which is directed to a "side-by –side" embodiment. Finally, Albee teaches that subparts 11 and 12 of Figure 3 show tension members to broken knee caps:

> Numbers 11 and 12 are keyed-in tension members in **broken knee caps** which will not join.
>
> [Albee at p. 179, caption to Figure 3; emphasis added in bold.]

Because the broken knee caps are in the patient (each half being joined by opposing ligaments), only the **single** dovetail or the I piece is implanted. There is no "assembled implant" that exists outside the body that is "suitable for implantation."

Regarding claim 116, the Patent Office contends that subpart 15 of Figure 3 is a "mirror image." To the extent that subpart 15 is a mirror image, it is a mirror image of two pieces of joined wood. It is not an "assembled implant" composed of cortical bone portions, wherein the assembled implant is "suitable for implantation in a patient." Further, as shown, it could not be a mirror image repair in the body because the opposing ends of the bone would be inherently different. In addition, it could not be a repair to a single bone because the bone would have to break exactly in that shape or be undesirably shortened by sawing the broken ends of the bone to achieve the overlapping shape. For this reason, subpart 15, which is directed to pieces of wood, would not be anticipatory of any of the Applicants' claims, including claim 116.

Lastly, the patent Office contends that regarding claim 121 that "figures 11-12 are sized and shaped in the form of a cervical implant." [Official Action at page 3.] The Applicants respectfully agree. As already discussed above, Albee expressly discloses that subparts 11 and 12 of Figure 3 are "knee caps" *in vivo* having tension members inserted. [Albee at caption to Figure 3; emphasis added in bold.] They are not assembled implants. as a practical matter, one skilled in the art recognizes that knee caps are much too large for insertion between any vertebrae and particularly cervical vertebrae. Their overall large size would cause them to either protrude from the vertebrae or sever the spinal cord of the recipient.

For all these reason, Albee would not be anticipatory of any of claims 111-118, (withdrawn claim 119), 120-123, and 126-127 of the present invention.

IV. 35 U.S.C. § 103(a), Coates over Siebels

Claims 111-118 and 120-128 are rejected under 35 U.S.C. § 103(a) over U.S. Pat. 5,989,289 (Coates) in view of EP 517030 (Siebels). According to the Patent Office, "[r]eferring to all figures, Coates teaches a D-shaped cortical bone spinal implant. . . ." [Official Action at pages 4 citing to Coates at col. 11, lines 42 et seq.] The Patent Office admits that "**Coates et al fails to teach said implant can comprise a first and**

second portion capable of being connected by a pin." [Official Action at page 4; emphasis added in bold.] To make up for this deficiency, the Patent Office cites to Siebels, stating that Siebels discloses "a spinal implant and teaches stacking portions 11 of the implant and connecting said portions with pins 17." [Official Action at page 4.] The Patent Office then concludes that "[i]t would have been obvious to one skilled in the art to have utilized the teachings of Siebels to stack and connect the individual implant portions with the D-shaped cortical bone implant of Coates wherein multiple portions could be stacked and connected by at least one pin in corresponding through holes to adjustably build the implant to a desired height (thickness) to best fill the disk space as desired by the surgeon." [Official Action at page 4.] The Applicants respectfully disagree.

In order for an invention to be obvious, "Both the suggestion and the **expectation of success** must be founded in the **prior art**, not in applicant's disclosure." *Amgen v. Chugai,* 18 USPQ2d 1016, 1022 (Fed. Cir. 1991); emphasis added in bold. In the present case, Siebels discloses that it was an object of their invention to make an implant that can "**easily** be manufactured for a multiplicity of overall dimensions:"

> Therefore, the objective to develop an implant of the kind mentioned at the outset, which can rapidly be implanted and which - from the standpoint of manufacturing engineering - can also **easily be manufactured** for a multiplicity of overall dimensions, forms the basis of the [proposed] invention.
>
> In accordance with the invention, the set objective is achieved with the help of the features, cited in claim 1.
>
> [English Translation of Siebels at page 2, line 20 to page 3, line 1; emphasis added in bold.]

To achieve the "ease" of manufacturing, Siebels relies upon cutting discs out of "**prefabricated solid or hollow strand.**" [English Translation of Siebels at page 3, line 7.] Specifically, Siebels discloses that this mode of manufacturing, comprising cutting appropriately sized strands made of "**fiber reinforced plastic**" provides for "manufacturing" in a "**extraordinarily easy way**":

> The disk-shaped implant is preferably made of **fiber-reinforced plastic** [FRP]. In accordance with a preferred embodiment of the invention, in order to produce a single-piece implant, the disk is **cut** out of a hollow strand, which consists of a **multiple number of braiding layers [plaiting layers]. The braiding layers, are wound up one after another on a correspondingly shaped mandrel** [arbor], preferably on a mandrel, having rectangular cross-section and rounded corners, directly in a braiding machine. The **disks are cut off with the desired height**, which can vary over the disk. Implants of this kind are characterized in that they can be **manufactured** in an **extraordinarily easy way**, in which the **fiber orientation** equally imparts an **optimal rigidity** and strength to the implant.
>
> [English Translation of Siebels at page 3, line 22 to page 4, line 9; emphasis added in bold.]

Thus, the heart of Siebel's invention is a prefabricated template that can be cut into directly useable slices to produce an implant "in an **extraordinarily easy way**." By use of the adjective "extraordinary," Siebels meant to convey that the disclosed process of manufacturing plastic implants was not just "**easy**" but "**extraordinarily easy**."

In addition, the above quote from Siebels teaches that "fiber orientation" is important because it "imparts an **optimal** rigidity." The word "optimal" is a superlative and means "most favorable or desirable; **best**; optimum." [Exhibit B: Webster's New World Dictionary, Second College Edition, Ed. Guralnik, Prentice Hall Press, 1986 at page 999; emphasis added in bold.] Thus, fiber orientation is a necessary element in the material used by Siebels to "impart optimal rigidity."

In contrast to the "**extraordinarily easy**" method of manufacturing disclosed in Siebels (that provides for an implant having "**optimal rigidity**"), Coates discloses that "developing an implant having the biomechanical properties of metal and the biological properties of bone without the disadvantages of either has been **extremely difficult** or **impossible**." [Coates at col. 3, lines 35-39.] By this statement, Coates teaches that as of its filing date (October 1995), cortical bone was not a "traditional orthopedic implant material" for spinal implants. It was considered "**extremely difficult or**

impossible" to provide an implant that had the benefits of both bone and metal without their undesired properties. The words "**extremely difficult or impossible**" are superlatives related to difficulty or impossibility. Given this "**extremely difficult or impossible**" setting, one would not have been motivated to substitute the cortical bone of Coates for the preformed plastic of Siebels. Given the art recognized **extreme difficulty** or **impossibility**, one skilled in the art would have even been less motivated to build an implant from little pieces of bone held together with pins, and there would not have been a reasonable expectation of success that the Applicants' would have been able to make implants for use in the spine from assembled pieces of cortical bone. *See Amgen v. Chugai,* 18 USPQ2d at 1022. For these reasons, claims 111-118 and 120-128 would not have been obvious under 35 U.S.C. § 103(a) over U.S. Pat. 5,192,327 (Brantigan) in view of U.S. Pat. 5,989,289 (Coates).

For this reason and all of the above reasons, the combination of Coates and Siebels would have failed to render obvious claims 111-118 and 120-128 at the time that the Applicants' invention was made.

V. 35 U.S.C. § 103(a), Brantigan over Coates

Claims 111-118 and 120-128 are rejected under 35 U.S.C. § 103(a) over U.S. Pat. 5,192,327 (Brantigan) in view of U.S. Pat. 5,989,289 (Coates). According to the Patent Office, Figures 2 and 5 of Brantigan teach a D-shaped implant comprising:

> a first portion 21;
>
> a second portion 21;
>
> said first portion and said second portion having one or more through holes 24 sized and positioned for receiving one or more retention pins 15 for connecting said first ~~cortical bone~~ [sic] portion to said second ~~cortical bone~~ [sic] portion; and
>
> one or more retention pins of appropriate diameter for connecting said first ~~cortical bone~~ [sic] portion to said second ~~cortical bone~~

[sic] portion to form said assembled bone implant unitary body.

[Official Action at page 5; strikeout corrections added.]

The above statement from the Patent Office is incorrect on its face because Brantigan never discloses any component or "portion" of an implant that is made of "cortical bone." In a later sentence in the Official Action, the Patent Office acknowledges that "Brantigan **fails to teach** that the **first and second portions are cortical bone.**" [Official Action at page 5; emphasis added in bold.] Thus, in the Patent Office's argument, the terms "said first cortical bone portion" and "said second cortical bone portion" lack antecedent basis and the resulting argument is indefinite. As a result, it is difficult to know what the Patent Office is contending.

1. When Brantigan is Properly interpreted, there is no Motivation to substitute the cortical bone of Coates for the "fiber reinforced plastic" in the implants of Brantigan

The Patent Office next contends that "[i]t would have been obvious to one of ordinary skill in the art to have used cortical bone which is a traditional, orthopaedic implant material as taught by Coates for any of the elements of Brantigan because '*5,192,327 to Brantigan teach hollow **metal** cage structures. Unfortunately, due to the stiffness of the material, some **metal** implants may stress shield the bone graft, increasing the time required for fusion or causing the bone graft to resorb inside the cage. Subsidence, or sinking of the device into bone, may also occur when metal implants are implanted between vertebrae if fusion is delayed. **Metal** devices are also foreign bodies which can never be fully incorporated into the fusion mass.*'" [Official Action at page 6.] The Applicants respectfully submit that Coates misinterprets Brantigan.

Specifically, Coates **teaches away** from the use of metals, just as Brantigan **teaches away** from metals. As a matter of law, "A prior art reference may be considered to teach away when 'a person of ordinary skill, upon reading the reference, would be **discouraged from following the path set out in the reference**, or would be led in a

direction divergent from the path taken by the applicant." *Monarch Knitting v. Sulzer*, 45 USPQ2d 1977, 1984 (Fed. Cir. 1998) (emphasis added in bold.). In particular, Brantigan teaches that fiber reinforced plastics are "preferred" over metals:

> The implants are **preferably** made of **radiolucent** material such as **carbon fiber reinforced polymers** known commercially as "Peek", (polyetherether ketone) or "Ultrapek" (polyether ketone, ether ketone, ketone). **Alternately**, polycarbonate, polypropylene, polyethylene and polysulfone type **plastics** material filled with **glass or carbon fibers** can be used. Such materials are supplied by ICI Industries of Wilmington, Del.; Fiber-Rite Corporation of Winona, Minn. or BASF Corporation.
>
> [Brantigan at col. 3, lines 9-18; emphasis added in bold.]

In fact, other than in Brantigan's Abstract, Brantigan never mentions the five specific metals (that are the traditional orthopaedic materials). Thus, Brantigan taught away from the use of metals by teaching that **fiber reinforced plastic** (as also used in Siebels), is a preferred alternative to metals. Coates never addressed Brantigan's primary disclosure, which is directed to the use of fiber reinforced plastics which is the heart of Brantigan's invention. Further, Coates' arguments at col. 2, lines 54-65 regarding the stress shielding caused by the stiffness of titanium alloys (114Gpa) and 316L stainless steel (193Gpa) versus cortical bone (about 17Gpa) do not apply to the carbon fiber reinforced PEEK (17.8 Gpa), carbon fiber reinforced polyetherketoneetherketoneketone (PEKEKEKK) (6.9-29.4 Gpa) or carbon fiber reinforced polycarbonate (4.1-21.4 Gpa) as disclosed in Brantigan at col. 3, lines 9-13. [See Exhibit A: from www.matweb.com at page 2, line 10 "Flexural modulus".] These fiber reinforced polymers have a stiffness (e.g. 17.8 Gpa) that is analogous to the stiffness cortical bone (about 17 Gpa) and substantially less than the stiffness (114-193 Gpa) of the recited metals. Thus, the fiber reinforced plastics of Brantigan do not have the disadvantage of "stress shielding" that is associated with metals. Further, the fiber reinforced plastics of Brantigan (and Siebel) offer yet another advantage of cortical bone because, unlike metals, both are transparent to X-rays. (See Coates at col. 2, lines 62-65 ("Moreover, **bone** as an implant also allows excellent postoperative imaging

because it **does not cause scattering like metallic implants on CT or MRI** imaging."); Brantigan at col. 3, lines 9-10 ("The implants are preferably made of **radiolucent material** such as **carbon fiber reinforced polymers** known commercially as 'Peek' (polyetheretherketone) or 'ultrapeek' (polyether ketone, ether ketone, ketone)"); and Siebel – Eng translation at page 6, 2nd full ¶ ("Preferably, the disks are made of a **carbon-fiber reinforced plastic (CFP)** whereby the anchoring means - according to the design of the implant - can consist of the same, or another material. The manufacturing of the entire implant of CFP has the advantage that **the implant does not bring about any scattering of rays**, so that the spinal column and the adjacent biological tissue can also be examined after the implantation of a spinal-column replacement with the help of **all image-producing methods (CT, MR)**;" emphasis added in bold). Thus, Coates misstates the teaching in Brantigan, which is not limited to metal implants, but rather is directed as its preferred embodiment to implants made from "carbon fiber reinforced plastic." Hence, one skilled in the art, upon reading both Coates and Brantigan, would not have been motivated to substitute the cortical bone of Coates for the fiber reinforced plastic of Brantigan, which Coates never discussed.

2. There is No Suggestion to Substitute Cortical Bone for Plastic or a Reasonable Expectation of Success

The Patent Office next contends that it "would have been obvious to one having ordinary skill in the art to have utilized **cortical bone which is a traditional orthopedic implant material** as taught by Coates for any of the elements of Brantigan." The Applicants respectfully disagree.

In order for an invention to be obvious, "Both the suggestion and the **expectation of success** must be founded in the **prior art**, not in applicant's disclosure." *Amgen v. Chugai,* 18 USPQ2d 1016, 1022 (Fed. Cir. 1991); emphasis added in bold. In the present case, at the time of Brantigan's 1991 filing date, Brantigan expressly teaches that the traditional orthopedic materials for spinal implants were "**nickel, chromium, cobalt, stainless steel or titanium.**" [Brantigan at the Abstract, last two lines.] At the

time of Coates' earliest claimed filing date (October 1995), Coates teaches that "developing an implant having the biomechanical properties of metal and the biological properties of bone without the disadvantages of either has been **extremely difficult** or **impossible.**" [Coates at col. 3, lines 35-39.] Thus, at the filing date (October 1995) of Coates, Coates teaches that cortical bone was not a "traditional orthopedic implant material" for spinal implants. It was considered "**extremely difficult or impossible**" to provide an implant that had the benefits of both bone and metal without their undesired properties. Given this "**extremely difficult or impossible**" setting, there would not have been a reasonable expectation of success that the Applicants' would have been able to make implants for use in the spine from assembled pieces of cortical bone. For these reasons, claims 111-118 and 120-128 would not have been obvious under 35 U.S.C. § 103(a) over U.S. Pat. 5,989,289 (Coates) in view of EP 517030 (Siebels)..

3. Even if Combined, the Combination of Coates and Brantigan would not make a *prima facie* case of Obviousness

Independent claim 111 of the Applicants' invention includes as elements the following:

> said first cortical bone portion and said second cortical bone portion having one or more **through holes sized** and positioned **for receiving one or more retention pins** for connecting said first cortical bone portion to said second cortical bone portion; and
>
> one or more **retention pins** of **appropriate diameter** for connecting said first cortical bone portion to said second cortical bone portion to form said assembled bone implant as a unitary body.
>
> [Claim 111: emphasis added in bold.]

Thus, one of the elements of Applicant's claim 111 is a "**retention pin** of **appropriate diameter**." Independent claim 120 also recites the same term "retention pin". One skilled in the art recognizes that the ordinary meaning of the term "diameter" means that the retention

pin has a substantially circular cross section. This is also seen in the circular "through holes" 701-704 of Applicants' FIG. 7A. In contrast, Brantigan does not teach or suggest the use of any "pins" of any "diameter." Rather, Brantigan discloses the use of a "**rectangular connecting bar**" of FIG. 3 to interconnect a plurality of D-shaped plastic devices of FIG. 2 in stacked array as shown in FIG. 5 of Brantigan:

> These grooves are provided for mounting a **rectangular connecting bar 15** shown in **FIG. 3**. This **bar 15 has flat side faces** 15a, rounded side edges 15b to snugly fit the grooves 14. . . .
>
> [Brantigan at col. 4, lines 25-28; emphasis added in bold.]

The Patent Office has acknowledged that Coates "fails to teach said implant can comprise a first and second portion capable of being connected by a pin." [Official Action at page 4.] Thus, the combination of Coates and Brantigan fail to teach or suggest an essential element of claim 111, *i.e.*, a "retention pin" having a rounded cross section of "appropriate diameter" for the through hole. Likewise independent claim 126 also recites as an element a "retention pin." Claims 112-118, 120-125 and 127-128, which ultimately depend from claims 111 and 126, would also incorporate the limitation to a "retention pin" by reference thereto. Accordingly, claims 111-118 and 120-128 would not have been obvious over the combination of Coates and Brantigan.

CONCLUSION

The provisional rejection of all claims of this restricted invention for double patenting over all claims of a separately restricted sister application will be address at such time as claims in one of the applications has been allowed. The rejection of claim 117 under 35 U.S.C. § 112, second paragraph, for indefiniteness has been rendered moot by amendment herein. The rejection of claims 111-118, 120-123 and 126-127 under 35 U.S.C. § 102(b) over Albee have been rebutted by evidence and arguments herein. The rejection of claims 111-118 and 120-128 under 35 U.S.C. § 103(a) over U.S. Pat. 5,989,289 (Coates) in view of EP 517030 (Siebels) have been rebutted by evidence and

arguments herein. Finally, the rejection of claims 111-118 and 120-128 under 35 U.S.C. § 103(a) over U.S. Pat. 5,192,327 (Brantigan) in view of U.S. Pat. 5,989,289 (Coates) have been rebutted by evidence and arguments herein.

The allowance of claims 111-118 and 120-128 is respectfully requested.

Respectfully submitted,

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		SGL Carbon Group 30% SIGRAFIL C® - filled PEEK	Overview - Polyetherketoneetherketoneketone (PEKEKK), Carbon Fiber Filled	Overview - Polycarbonate, Carbon Fiber Reinforced
Physical				
1	Density (g/cc)	1.4	1.33 - 1.41	1.21 - 1.39
2	Water Absorption (%)	0.17	0.1 - 0.2	0.08 - 0.2
3	Linear Mold Shrinkage (cm/cm)	--	0.0005 - 0.001	0.0005 - 0.0053
4	Linear Mold Shrinkage, Transverse (cm/cm)	--	0.015	--
Mechanical				
5	Hardness, Rockwell R	--	--	118 - 120
6	Tensile Strength, Ultimate (MPa)	218	183 - 269	83 - 200

7	Tensile Strength, Yield (MPa)	--	--	110
8	Elongation at Break (%)	1.6	1.4 - 2.5	1.5 - 8
9	Modulus of Elasticity (GPa)	--	12.4 - 26.2	4.8 - 24.1
10	Flexural Modulus (GPa)	17.8	6.9 - 21.4	4.1 - 21.4
11	Flexural Yield Strength (MPa)	297	270 - 379	124 - 296
12	Compressive Yield Strength (MPa)	--	--	114 - 152
13	Izod Impact, Notched (J/cm)	--	1 - 1.1	0.48 - 1.87
14	Izod Impact, Notched (ISO) (kJ/m²)	9	--	--
15	Izod Impact, Unnotched (J/cm)	--	8 - 9.1	2.94 - 9.5
16	Izod Impact, Unnotched (ISO) (kJ/m²)	43.2	--	--
17	K (wear) Factor	--	5000	--
Electrical				
18	Electrical Resistivity (ohm-cm)	5500	100000	5 - 1e+010
19	Surface Resistance (ohm)	--	--	5 - 1e+010
Thermal				
20	CTE, linear 20°C (µm/m-°C)	--	--	13 - 31
21	Thermal Conductivity (W/m-K)	--	--	0.55 - 0.72
22	Maximum Service Temperature, Air (°C)	--	--	100 - 149
23	Deflection Temperature at 0.46 MPa (66 psi) (°C)	--	--	141 - 151
24	Deflection Temperature at 1.8 MPa (264 psi) (°C)	--	271 - 354	100 - 149

25	Glass Temperature (°C)	--	--	150
26	Flammability, UL94	--	V-0	HB - V-0
Processing				
27	Processing Temperature (°C)	--	--	300 - 318
28	Mold Temperature (°C)	--	--	85 - 121
29	Drying Temperature (°C)	--	--	120
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SECOND COLLEGE EDITION

WEBSTER'S NEW WORLD DICTIONARY

OF THE AMERICAN LANGUAGE

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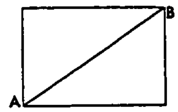
di·ag·o·nal (dī ag′ə n'l) *adj.* [L. *diagonalis* < Gr. *diagōnios* < *dia-*, through + *gōnia*, an angle, corner: for IE. base see KNEE] 1. extending between the vertices of any two nonadjacent angles in a polygonal figure or between any two vertices not in the same face in a polyhedral figure; extending slantingly between opposite corners 2. moving or extending obliquely, esp. at a 45° angle; slanting 3. having slanting markings, lines, etc. —*n.* 1. *a*) a diagonal line or plane *b*) *same as* VIRGULE 2. any diagonal course, row, order, or part 3. cloth woven with diagonal lines; twill —**di·ag′o·nal·ly** *adv.*



DIAGONAL

di·a·gram (dī′ə gram′) *n.* [Gr. *diagramma* < *diagraphein*, to mark out by lines, draw < *dia-*, through, across + *graphein*, to write: see GRAPHIC] 1. a geometrical figure, often used to illustrate a theorem 2. a sketch, drawing, or plan that explains a thing by outlining its parts and their relationships, workings, etc. 3. a chart or graph explaining or illustrating ideas, statistics, etc. —*vt.* **-gramed′** or **-grammed′**, **-gram′ing** or **-gram′ming** to show or represent by a diagram; make a diagram of —**di′a·gram·mat′ic** (-grə mat′ik), **di′a·gram·mat′i·cal** *adj.* —**di′a·gram·mat′i·cal·ly** *adv.*

di·a·ki·ne·sis (dī′ə ki nē′sis) *n.* [ModL. < DIA- + Gr. *kinēsis*, motion: see KINEMATICS] in the meiosis of germ cells, a stage in which the maternal and paternal chromosomes have paired within the nucleus —**di′a·ki·net′ic** (-net′ik) *adj.*

di·al (dī′əl, dīl) *n.* [ME. < ML. *dialis*, daily < L. *dies*, day: see DEITY] 1. a sundial 2. the face of a watch or clock 3. the face of a meter, gauge, compass, etc. on which a pointer or the like indicates an amount, degree, direction, etc. 4. a graduated disk on a radio, or television set, esp. one for tuning in stations or channels ☆5. a rotating disk on a telephone, used in making connections automatically —*vt.*, *vi.* **-aled** or **-alled**, **-al·ing** or **-al·ling** 1. to measure with or as with a dial 2. to show on a dial 3. to tune in (a radio station, television channel, program, etc.) ☆4. to call on a telephone by using a dial

dial. 1. dialect(al) 2. dialectic(al)

di·a·lect (dī′ə lekt′) *n.* [L. *dialectus* < Gr. *dialektos*, discourse, discussion, dialect < *dialegesthai*, to discourse, talk < *dia-*, between + *legein*, to choose, talk: see LOGIC] 1. the sum total of local characteristics of speech 2. the sum total of an individual's characteristics of speech; idiolect 3. any form of speech considered as deviating from a real or imaginary standard speech 4. the form or variety of a spoken language peculiar to a region, community, social group, occupational group, etc.: in this sense, *dialects* are regarded as being, to some degree, mutually intelligible while *languages* are not mutually intelligible 5. any language as a member of a group or family of languages [English is a West Germanic *dialect*] —*adj.* of or in dialect [*dialect* ballads] —**di′a·lec′tal** *adj.* —**di′a·lec′tal·ly** *adv.*

SYN.—**dialect**, in this comparison, refers to a form of a language peculiar to a locality or group and differing from the standard language in matters of pronunciation, syntax, etc.; **vernacular** today commonly refers to the informal or colloquial variety of a language as distinguished from the formal or literary variety; **cant**, in this connection, refers to the distinctive stock words and phrases used by a particular sect, class, etc. [clergymen's *cant*]; **jargon** is used of the special vocabulary and idioms of a particular class, occupational group, etc., esp. by one who is unfamiliar with these; **argot** refers esp. to the secret jargon of thieves and tramps; **lingo** is a humorous or mildly contemptuous term applied to any language, dialect, or jargon by one to whom it is unintelligible

dialect atlas *same as* LINGUISTIC ATLAS

dialect geography *same as* LINGUISTIC GEOGRAPHY

di·a·lec·tic (dī′ə lek′tik) *n.* [ME. *dialetik* < OFr. *dialetique* < L. *dialectica* (*ars*) < Gr. *dialektikē* (*technē*), the dialectic (art) < *dialektikos*: see DIALECT] 1. [*often pl.*] the art or practice of examining opinions or ideas logically, often by the method of question and answer, so as to determine their validity 2. logical argumentation 3. [*often pl.*] *a*) the method of logic used by Hegel and adapted by Marx to observable social and economic processes: it is based on the principle that an idea or event (*thesis*) generates its opposite (*antithesis*) leading to a reconciliation of opposites (*synthesis*) *b*) the general application of this principle in analysis, criticism, exposition, etc. —*adj.* *same as* DIALECTICAL

di·a·lec·ti·cal (-ti k'l) *adj.* 1. of or using dialectic or dialectics 2. of or characteristic of a dialect; dialectal —**di′a·lec′ti·cal·ly** *adv.*

dialectical materialism the philosophy stemming from Marx and Engels which applies Hegel's dialectical method to observable social processes and to nature

di·a·lec·ti·cian (dī′ə lek tish′ən) *n.* [Fr. *dialecticien*] 1. an expert in dialectic; logician 2. a specialist in dialects

di·a·lec·tol·o·gy (-täl′ə jē) *n.* the scientific study of dialects —**di′a·lec·tol′o·gist** *n.* —**di′a·lec′to·log′i·cal** (-tə läj′i k'l) *adj.* —**di′a·lec′to·log′i·cal·ly** *adv.*

di·al·lage (dī′ə lij) *n.* [Fr. < Gr. *diallagē*, change, interchange < *diallassein*, to interchange < *dia*, through + *allassein*, to alter < *allos*, other (see ELSE): so named from having unlike fracture planes] a dark-green mineral that is a laminated variety of pyroxene

di·a·log (dī′ə lôg′, -läg′) *n.*, *v.* *same as* DIALOGUE

di·a·log·i·cal (dī′ə läj′i k'l) *adj.* of or marked by dialogue: also **di′a·log′ic** —**di′a·log′i·cal·ly** *adv.*

di·al·o·gist (dī al′ə jist, dī′ə lôg′ist, -läg′-) *n.* 1. a writer of dialogue 2. a person who takes part in a dialogue —**di·al·o·gis·tic** (dī′ə lô jis′tik) *adj.*

di·a·logue (dī′ə lôg′, -läg′) *n.* [ME. *dialog* < OFr. *dialogue* < L. *dialogus* < Gr. *dialogos* < *dialegesthai*: see DIALECT] 1. a talking together; conversation 2. interchange and discussion of ideas, esp. when open and frank, as in seeking mutual understanding or harmony 3. a written work in the form of a conversation 4. the passages of talk in a play, story, radio act, etc. —*vi.* **-logued′**, **-logu′ing** to hold a conversation —*vt.* to express in dialogue

Dialogue Mass *R.C.Ch.* a Low Mass at which the congregation, following an earlier custom now revived, makes the responses aloud and in unison

☆**dial tone** a low buzzing sound indicating to the user of a dial telephone that the line is open and a number may be dialed

di·al·y·sis (dī al′ə sis) *n.*, *pl.* **-ses′** (-sēz′) [L. < Gr., separation, dissolution < *dialyein*, to separate, dissolve < *dia-*, apart + *lyein*, LOOSE] the separation of crystalloids or dissolved substances from colloids in solution by the greater diffusibility of the smaller molecules through a semipermeable membrane: used as in the mechanical elimination of impurities from the blood during kidney failure —**di·a·lyt·ic** (dī′ə lit′ik) *adj.* —**di′a·lyt′i·cal·ly** *adv.*

di·a·lyze (dī′ə līz′) *vt.* **-lyzed′**, **-lyz′ing** to apply dialysis to or separate by dialysis —*vi.* to undergo dialysis

di·a·lyz·er (-lī′zər) *n.* an apparatus for dialyzing, esp. one used as an artificial kidney

diam. diameter

di·a·mag·net·ic (dī′ə mag net′ik) *adj.* having or relating to diamagnetism —*n.* a diamagnetic substance, as bismuth or zinc: also **di′a·mag′net**

di·a·mag·net·ism (-mag′nə tiz'm) *n.* 1. the property that certain substances have of being repelled by both poles of a magnet and hence taking a position at right angles to the magnet's line of influence 2. diamagnetic force 3. diamagnetic phenomena 4. the science that deals with such phenomena and substances

di·a·man·té (dē′ə män tā′, -män′tā; *Fr.* dyä män tā′) *adj.* [Fr. < pp. of *diamanter*, to tinsel, lit., set with diamonds < *diamant*, DIAMOND] decorated with rhinestones or with other brightly glittering bits of material [*diamanté* sandals] —*n.* glittering ornamentation

di·am·e·ter (dī am′ət ər) *n.* [ME. & OFr. *diametre* < ML. *diametra* < L. *diametrus* < Gr. *diametros* < *dia-*, through + *metron*, a measure: see METER¹] 1. a straight line passing through the center of a circle, sphere, etc. from one side to the other 2. the length of such a line; width or thickness of a circular, or somewhat circular, figure or object 3. *Optics* the unit of measure of the magnifying power of a lens

di·a·met·ri·cal (dī′ə met′ri k'l) *adj.* 1. of or along a diameter: also **di·am·e·tral** (dī am′ə trəl) 2. designating an opposite, a contrary, a difference, etc. that is wholly so; complete [*diametrical* opposites]: also **di′a·met′ric** —**di′a·met′ri·cal·ly** *adv.*

di·am·ine (dī am′ēn, -in; dī′ə mēn′) *n.* any of a group of chemical compounds containing two NH_2 radicals; double amine

di·a·mond (dī′mənd, -ə mənd) *n.* [ME. *diamaunt* < OFr. *diamant* < ML. *diamas* (gen. *diamantis*), for L. *adamas* < Gr. *adamas*, adamant, diamond] 1. a mineral consisting of nearly pure carbon in crystalline form, usually colorless, the hardest natural substance known: transparent, unflawed stones are cut into precious gems of great brilliance; less perfect forms are used for cutting tools, abrasives, phonograph-needle tips, etc. 2. a gem or other piece cut from this mineral 3. *a*) a lozenge-shaped plane figure (◊) *b*) a red mark like this, used for one of the four suits of playing cards *c*) [*pl.*] this suit *d*) a card of this suit ☆4. *Baseball* *a*) the infield *b*) the whole playing field —*adj.* of, like, or set with a diamond or diamonds —*vt.* to adorn with or as with diamonds —**diamond in the rough** 1. a diamond in its natural state 2. a person or thing of fine quality but lacking polish

diamond anniversary the sixtieth, or sometimes seventy-fifth, anniversary of an event

di·a·mond·back (-bak′) *adj.* having diamond-shaped markings on the back —*n.* ☆1. a large, poisonous rattlesnake (*Crotalus adamanteus*) with diamond-shaped markings on its back, native to the S U.S. ☆2. an edible turtle (*Malaclemys terrapin*) with diamond-shaped markings on its shell, found in coastal salt marshes from Cape Cod to Mexico: in full, **diamondback terrapin** 3. a small, brown and white cosmopolitan moth (*Plutella maculipennis*) whose wings, when folded, form a diamond

Diamond Head promontory in Honolulu, Hawaii

optic axis in a crystal not having the same properties in all directions with regard to light, a direction along which there is no apparent double refraction since both components of the light ray have the same velocity
optic disk *same as* BLIND SPOT (sense 1)
op·ti·cian (äp tish′ən) *n.* [Fr. *opticien*] a person who makes or deals in optical instruments, esp. one who prepares and dispenses eyeglasses
optic nerve either of the second pair of cranial nerves, which connect the retina of the eye with the brain
op·tics (äp′tiks) *n.pl.* [*with sing. v.*] [< OPTIC] the branch of physics dealing with the nature and properties of light and vision
op·ti·mal (äp′tə məl) *adj.* [OPTIM(UM) + -AL] most favorable or desirable; best; optimum —**op′ti·mal·ly** *adv.*
op·ti·mism (-miz′m) *n.* [Fr. *optimisme* < L. *optimus*, best (see OPTIMUM)] 1. *Philos.* *a)* the doctrine held by Leibniz and others that the existing world is the best possible *b)* the doctrine or belief that good ultimately prevails over evil 2. the tendency to take the most hopeful or cheerful view of matters or to expect the best outcome; practice of looking on the bright side of things —**op′ti·mist** (-mist) *n.* —**op′ti·mis′tic** (-mis′tik), **op′ti·mis′ti·cal** *adj.* —**op′ti·mis′ti·cal·ly** *adv.*
op·ti·mize (-mīz′) *vi.* **-mized′, -miz′ing** to be given to optimism —*vt.* to make the most of; develop or realize to the utmost extent; obtain the most efficient or optimum use of —**op′ti·mi·za′tion** *n.*
op·ti·mum (-məm) *n., pl.* **-mums, -ma** (-mə) [L., neut. of *optimus*, best < *ops*, power, riches: for base see OPUS] 1. the best or most favorable degree, condition, amount, etc. 2. *Biol.* the amount of heat, light, moisture, food, etc. most favorable for growth and reproduction —*adj.* most favorable or desirable; best; optimal
op·tion (äp′shən) *n.* [Fr. < L. *optio* < *optare*, to wish, desire, ult. < IE. base *op-, to choose, prefer] 1. the act of choosing: choice 2. the power, right, or liberty of choosing 3. something that is or can be chosen; choice 4. the right, acquired for a consideration, to buy, sell, or lease something at a fixed price, sign or renew a contract, etc. within a specified time —☆*vt.* *Sports* to transfer (a player) to a minor league with the option of recalling him —*SYN.* see CHOICE
op·tion·al (-'l) *adj.* left to one's option, or choice; not compulsory; elective —**op′tion·al·ly** *adv.*
op·to·e·lec·tron·ics (äp′tō i lek′trän′iks) *n.pl.* a branch of electronics involving the use of optical technology —**op′to·e·lec′tron′ic** *adj.*
op·tom·e·ter (äp täm′ə tər) *n.* [see OPTIC & -METER] an instrument for determining error in the refractive power of the eye
☆**op·tom·e·trist** (-trist) *n.* a specialist in optometry
op·tom·e·try (-trē) *n.* [see OPTIC & -METRY] 1. measurement of the range and power of vision 2. the profession of examining the eyes and measuring errors in refraction and of prescribing glasses to correct these defects —**op·to·met·ric** (äp′tə met′rik), **op′to·met′ri·cal** *adj.*
op·u·lent (äp′yə lənt) *adj.* [L. *opulentus* or *opulens* < *ops*: see OPUS] 1. very wealthy or rich 2. characterized by abundance or profusion; luxuriant —*SYN.* see RICH —**op′u·lence, op′u·len·cy** *n.* —**op′u·lent·ly** *adv.*
o·pun·ti·a (ō pun′shē ə, -shə) *n.* [ModL. < L. (*herba*) *Opuntia*, (plant) of Opus, city in Locris, Greece] any of a large genus (*Opuntia*) of cactus plants with red, purple, or yellow flowers, pulpy or dry berries, and fleshy, jointed stems, including the prickly pears and chollas
o·pus (ō′pəs) *n., pl.* **o·pe·ra** (ō′pə rə, äp′ər ə), **o′pus·es** [L., a work < IE. *ops < base *op-, to work, riches, whence L. *ops*, riches, Sans. *ápas-*, work, OE. *efnan*, to work, do] a work; composition; esp., any of the musical works of a composer numbered in order of composition or publication
o·pus·cule (ō pus′kyo͞ol) *n.* [Fr. < L. *opusculum*, dim. of *opus*: see prec.] a minor work —**o·pus′cu·lar** *adj.*
-o·py (ō′pē) *same as* -OPIA
☆**o·quas·sa** (ō kwas′ə) *n.* [< *Oquassa* Lake, in Maine] a small trout (*Salvelinus oquassa*) of lakes of W Maine
or[1] (ôr; *unstressed* ər) *conj.* [ME., in form a contr. of *other*, *auther*, either, but actually < OE. *oththe* (in *āther* . . . *oththe*, either . . . or)] a coordinating conjunction introducing an alternative; specif., *a)* introducing the second of two possibilities [*beer or wine*] *b)* introducing any of the possibilities in a series, but usually used only before the last [*apples, (or) pears, or plums*] *c)* introducing a synonymous word or phrase [*botany, or the science of plants*] *d)* introducing the second of two possibilities when the first is introduced by *either* or *whether* [*either go or stay, whether to go or stay*] *e)* substituted for *either* as the first correlative [*"or in the heart or in the head"*]
or[2] (ôr) *conj., prep.* [ME. < OE. *ār*, var. of *ǣr*, *ere*: cf. ERE] [Archaic or Dial.] before; ere
or[3] (ôr) *n.* [Fr. < L. *aurum*, gold: for IE. base see EAST] *Heraldry* gold or yellow, represented in engraving by small dots powdered over a plain field
-or (ər; *occas.* ôr) 1. [ME. *-our* < OFr. *-our, -or, -eur* < L. *-or, -ator*] *a n.-forming suffix meaning* a person or thing that [*inventor, objector*] 2. [ME. *-our* < OFr. < L. *-or*] *a n.-forming suffix meaning* quality or condition [*horror, error*]: in Brit. usage, often **-our**
‡**o·ra** (ôr′ə) *n. pl. of* OS[2]
or·ach, or·ache (ôr′əch, är′-) *n.* [ME. *orage* < Anglo-Fr. *orache* < OFr. *arroche* < VL. **atrapica* (for L. *atriplex*) < Gr. *atraphaxys*] any of a genus (*Atriplex*) of plants of the goosefoot family, widespread in salty or alkaline areas, having usually silvery foliage and small green flowers; esp., **garden orach** (*Atriplex hortensis*), cultivated as a potherb, chiefly in France
or·a·cle (ôr′ə k'l, är′-) *n.* [ME. < OFr. < L. *oraculum*, divine announcement, oracle < *orare*, to speak, pray, beseech < *os* (gen. *oris*), the mouth: see ORAL] 1. among the ancient Greeks and Romans, *a)* the place where, or medium by which, deities were consulted *b)* the revelation or response of a medium or priest 2. *a)* any person or agency believed to be in communication with a deity *b)* any person of great knowledge or wisdom *c)* opinion or statements of any such oracle 3. the holy of holies of the ancient Jewish Temple: I Kings 6:16, 19–23
o·rac·u·lar (ô rak′yoo lər) *adj.* 1. of, or having the nature of, an oracle 2. like an oracle; wise, prophetic, mysterious, etc. —**o·rac′u·lar′i·ty** (-yə lar′ə tē) *n.* —**o·rac′u·lar·ly** *adv.*
o·rad (ôr′ad) *adv.* [< L. *os* (gen. *oris*), the mouth + -AD[2]] toward the mouth or oral region
O·ra·dea (ô räd′yä) city in NW Romania, near the Hungarian border: pop. 112,000
o·ral (ôr′əl) *adj.* [< L. *os* (gen. *oris*), the mouth < IE. base *ōus-, mouth, edge, whence Sans. *ā́-ḥ*, mouth, ON. *ōss*, mouth of a stream] 1. uttered by the mouth; spoken 2. of speech; using speech 3. of, at, or near the mouth 4. *Phonet.* having mouth resonance only: distinguished from NASAL 5. *Psychoanalysis* *a)* designating or of the earliest stage of psychosexual development in which interest centers around sucking, feeding, and biting *b)* designating or of such traits in the adult as friendliness, generosity, and optimism or aggressiveness and pessimism, regarded as unconscious psychic residues of that stage: cf. ANAL, GENITAL 6. *Zool.* on or of the same side as the mouth —☆*n.* an examination that is oral and not written, as in a college —**o′ral·ly** *adv.*
SYN.—**oral** refers to that which is spoken, as distinguished from that which is written or otherwise communicated [*an oral promise, request, etc.*]; **verbal**, though sometimes synonymous with **oral**, in strict discrimination refers to anything using words, either written or oral, to communicate an idea or feeling [*a verbal image, caricature, etc.*]
oral history 1. historical data consisting of personal recollections, usually in the form of a tape-recorded interview 2. the gathering and preservation of such data
o·ral·ism (ôr′əl iz′m) *n.* the theory or practice of teaching the deaf to read lips and to speak —**o′ral·ist** *adj., n.*
O·ran (ō ran′; *Fr.* ô rän′) seaport in N Algeria, on the Mediterranean: pop. 430,000
o·rang (ō raŋ′, ə-) *n. same as* ORANGUTAN
Or·ange[1] (ôr′inj, är′-) ruling family of the Netherlands: see NASSAU —*adj.* of or having to do with Orangemen
Or·ange[2] (ôr′inj, är′-; *also, for 3 & 4, Fr.* ô ränzh′) 1. [prob. after the *orange* groves there] city in SW Calif.: suburb of Los Angeles: pop. 92,000 2. river in South Africa, flowing from NE Lesotho west into the Atlantic: c. 1,300 mi. 3. former principality of W Europe, now in SE France 4. city in SE France: pop. 21,000
or·ange (ôr′inj, är′-) *n.* [ME. < OFr. *orenge* < Pr. *auranja* (with sp. influenced by L. *aurum*, gold & loss of initial *n* through faulty separation of art. *un*) < Sp. *naranja* < Ar. *nāranj* < Per. *nārang* < Sans. *naranga*, prob. akin to Tamil *naṟu*, fragrant] 1. a reddish-yellow, round, edible citrus fruit, with a sweet, juicy pulp 2. any of various evergreen trees (genus *Citrus*) of the rue family producing this fruit, having white, fragrant blossoms, often carried by brides, and hard, yellow wood 3. any of several plants or fruits resembling the orange 4. reddish yellow —*adj.* 1. reddish-yellow 2. made with or from orange 3. having a flavor like that of oranges —**or′ang·y** (-in jē) *adj.*
or·ange·ade (-ād′) *n.* [Fr.: see ORANGE & -ADE] a drink made of orange juice and water, usually sweetened
Orange Free State province of South Africa, west of Lesotho: formerly a Boer republic (1854–1900) & then a Brit. colony (**Orange River Colony**, 1900–10): 49,866 sq. mi.; pop. 1,387,000; cap. Bloemfontein
☆**orange hawkweed** *same as* DEVIL'S PAINTBRUSH
Or·ange·ism (ôr′inj iz′m, är′-) *n.* the principles and practices of the Orangemen
Or·ange·man (-mən) *n., pl.* **-men** (-mən) [after the Prince of *Orange*, later WILLIAM III] a member of a secret Protestant society organized in N Ireland (1795)
orange pekoe a black tea of Ceylon and India: see PEKOE
or·ange·ry (ôr′inj rē, är′-) *n., pl.* **-ries** [Fr. *orangerie* < *oranger*, orange tree < *orange*] a hothouse or other sheltered place for growing orange trees in cooler climates
☆**orange stick** a pointed stick, orig. of orangewood, used in manicuring

UNITED STATES PATENT AND TRADEMARK OFFICE

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/905,683	07/16/2001	Jamie M. Grooms	197319US/222962US	4376

7590 06/17/2005

DONALD J. POCHOPIEN
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500 WEST MADISON STREET
CHICAGO, IL 60661

EXAMINER	
SNOW, BRUCE EDWARD	
ART UNIT	**PAPER NUMBER**
3738	

DATE MAILED: 06/17/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/905,683	GROOMS ET AL.	
	Examiner	**Art Unit**	
	Bruce E. Snow	3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 April 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *111-128* is/are pending in the application.

4a) Of the above claim(s) *119* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *111-118 and 120-128* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Response to Arguments

Applicant's arguments filed April 18, 2005, have been fully considered. Regarding the rejection under 35 U.S.C. 102(b) as being anticipated by Albee (Bone Surgery with Machine Tools), applicant notes that the Examiner is specifically referring to the subparts of Figure 3 which is correct, however, as stated in the rejections "refer to all figures". Applicant argues that Albee fails to teach an "assembled implant suitable for implantation into a patient". As shown in at least sub Figures 10, 11, and 12 of Figure 3, first and second cortical bone portions can be assembled via retention pins. It is the Examiner's position that such a surgery in vivo fulfills claim language "assembled bone implant as a unitary body" found in the body of the claim. Regarding the language "suitable for implantation into a patient" found in the preamble, it is not clear if that limitation breathes any life or meaning into the claim; all claim elements of Albee are implanted. Additionally, it is conceivable that an assembled first and second cortical bone portion via a retention pin could be implanted into a second patient via a donor surgery fulfilling all functional language. Secondly, in situations of multiple brakes, it is conceivable that bone portions are connected together outside of the body and than placed back, such as skull fractures. Specifically referring to sub figure 15, it is unclear if the elements being secured together are bone, however, clearly teaches that more than one pin of appropriate diameter can be used.

Regarding the limitation "diameter", this does not limit the pin to a cylindrical shape.

Applicant's argument regarding sub-Figures 11-12 not teaching a "superimposed" (as claimed in claim 126) is persuasive and the rejection of claims 126-128 has been withdrawn.

Regarding the rejection under 35 U.S.C. 103(a) as being unpatentable over Coates et al (5,989,289) in view of Siebels (EP 517030), applicant argues that Siebels teaches connecting (stacking) implant portions because it is easier to manufacture. In response to applicant's argument, the fact that Siebels recognized another advantage of their invention does not take away from the teaching and advantage of multiple portions stacked and connected by at least one pin in corresponding through holes to adjustably build the implant to a desired height (thickness) to best fill the disc space as desired by the surgeon.

Regarding the rejection under 35 U.S.C. 103(a) as being unpatentable over Brantigan (5,192,327) in view of Coates et al (5,989,289), applicant's arguments are not persuasive. **Coates specifically states that the implant of Brantigan is flawed because the materials used (including metals) of Brantigan are too stiff which causes stress shielding, etc., as stated in the grounds of rejection. Coates in the very next paragraph teaches bone as an implant material "avoid[s] the disadvantages of metal implants"; see column 2, lines 49 et seq.**

Double Patenting

All claims are provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of all claims of copending Application No. 10/375,540. This is a

provisional double patenting rejection since the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 111-118, 120-123 are rejected under 35 U.S.C. 102(b) as being anticipated by Albee (Bone Surgery with Machine Tools).

Referring to all figures, specifically figures 10-12 and 15, Albee teaches:

a first cortical bone portion;

a second cortical bone portion;

said first cortical bone portion and said second cortical bone portion having one or more through holes sized and positioned for receiving one or more retention pins for connecting said first cortical bone portion to said second cortical bone portion; and

one or more retention pins of appropriate diameter for connecting said first cortical bone portion to said second cortical bone portion to form said assembled bone implant unitary body.

Regarding figures 11-12, Albee teaches superimposed first and second cortical bone portions each have a D-shape having a through hole with receives the I shaped pin interpreted as having an appropriate diameter. Albee teaches the pines are grafts which inherently comprise cortical and cancellous bone.

Regarding claim 116, mirror image, see at least figure 15.

Regarding claim 121, the embodiments shown in figures 11-12 are sized and shaped for in the form of a cervical implant.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 111-118 and 120-128 are rejected under 35 U.S.C. 103(a) as being unpatentable over Coates et al (5,989,289) in view of Siebels (EP 517030).

Referring to all figures, Coates teaches a D-shaped cortical bone spinal implant (see column 11, lines 42 et seq.). However, Coates et al fails to teach said implant can comprise a first and second portion capable of being connected by a pin. Siebels also teaches a spinal implant and teaches stacking portions 11 of the implant and connecting said portions with pins 17. It would have been obvious to one having ordinary skill in the art to have utilized the teachings of Siebels to stack and connect individual implant portions with the D-shaped cortical bone implant of Coates wherein multiple portions could be stacked and connected by at least one pin in corresponding through holes to adjustably build the implant to a desired height (thickness) to best fill the disc space as desired by the surgeon.

Regarding at least claims 114-115, 123, and 127, lacking any criticality in the specification, the use of the claimed materials such as titanium in lieu of those taught by Seibels produce no advantage and is considered an obvious matter of design choice. Additionally, Coates teaches the use of metal devices are foreign bodies which can never be fully incorporated in the fusion mass and produce stress shielding because the stiffness values do not match that of bone (column 2, lines 34 et seq.). Therefore, it would have been obvious to one having ordinary skill in the art to have constructed the pin out of cortical bone or cancellous bone which can be fully incorporated and does not produce stress shielding.

Regarding claim 122, see column 11, lines 62 et seq.

Regarding claims 124 and 128, Coates et al teaches treating the spacer with BMP which would include the pins.

All other claimed limitations are self-evident.

Claims 111-118 and 120-128 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brantigan (5,192,327) in view of Coates et al (5,989,289).

Referring to all figures, specifically figures 2 and 5, Brantigan teaches a D-shaped bone implant comprising:

a first portion 21;

a second portion 21;

said first portion and said second portion having one or more through holes 24 sized and positioned for receiving one or more retention pins 15 for connecting said first cortical bone portion to said second cortical bone portion; and

one or more retention pins of appropriate diameter for connecting said first cortical bone portion to said second cortical bone portion to form said assembled bone implant unitary body.

However, Brantigan fails to teach the first and second portions are cortical bone. Brantigan teaches the device can be made of traditional orthopaedic implant materials; see the abstract. Coates et al teaches a D shaped implant can be made of cortical bone. It would have been obvious to one having ordinary skill in the art to have utilized cortical bone which is a traditional orthopaedic implant material as taught by Coates for any of the elements of Brantigan because "*5,192,327 to Brantigan teach hollow metal cage structures. Unfortunately, due to the stiffness of the material, some metal implants may stress shield the bone graft, increasing the time required for fusion or causing the bone graft to resorb inside the cage. Subsidence, or sinking of the device into bone, may also occur when metal implants are implanted between vertebrae if fusion is delayed. Metal devices are also foreign bodies which can never be fully incorporated into the fusion mass.*" See column 2, lines 40 et seq. of Coates.

Regarding at least claims 114-115, 123, and 127, the combination at least teaches titanium or cortical bone, lacking any criticality in the specification, the use of the specific use of any claimed materials for the pin in lieu of those taught by references produces no advantage and is considered an obvious matter of design choice.

Additionally, Coates teaches the use of metal devices are foreign bodies which can never be fully incorporated in the fusion mass and produce stress shielding because the stiffness values do not match that of bone (column 2, lines 34 et seq.). Therefore, it would have been obvious to one having ordinary skill in the art to have constructed the pin out of cortical bone or cancellous bone which can be fully incorporated and does not produce stress shielding.

Regarding claims 124 and 128, Coates et al teaches treating the spacer with BMP which would include the pins.

All other claimed limitations are self-evident.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bruce E Snow whose telephone number is (571) 272-4759. The examiner can normally be reached on Mon-Thurs.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on (571) 272-4754. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

bes

BRUCE SNOW
PRIMARY EXAMINER

Search Notes	Application No.	Applicant(s)
	09/905,683	GROOMS ET AL.
	Examiner	**Art Unit**
	Bruce E Snow	3738

SEARCHED

Class	Subclass	Date	Examiner
623	17.11		
	17.15		
	17.16		
606	61	3/15/2004	
updated Snow		12/1/04	BS
updated		6/13/05	BS

SEARCH NOTES (INCLUDING SEARCH STRATEGY)

	DATE	EXMR

INTERFERENCE SEARCHED

Class	Subclass	Date	Examiner
623	17.11		
	17.16	12/1/04	BS

09/905683

PATENT APPLICATION FEE DETERMINATION RECORD

Effective October 1, 2

CLAIMS AS FILED - PART I

	(Column 1)	(Column 2)
TOTAL CLAIMS		
FOR	NUMBER FILED	NUMBER EXTRA
TOTAL CHARGEABLE CLAIMS	58 minus 20=	* 38
INDEPENDENT CLAIMS	12 minus 3 =	* 9
MULTIPLE DEPENDENT CLAIM PRESENT		☐

* If the difference in column 1 is less than zero, enter "0" in column 2

SMALL ENTITY TYPE ☐ RATE	FEE	OR	OTHER THAN SMALL ENTITY RATE	FEE
BASIC FEE	355.00	OR	BASIC FEE	710.00
X$ 9=		OR	X$18=	684
X40=		OR	X80=	[illegible]
+135=		OR	+270=	
TOTAL		OR	TOTAL	2114

CLAIMS AS AMENDED - PART II

9-20-04

AMENDMENT A

	(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA
Total	* 18	Minus	** 58	= –
Independent	* 2	Minus	*** 12	= –
FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM				☐

SMALL ENTITY RATE	ADDITIONAL FEE	OR	OTHER THAN SMALL ENTITY RATE	ADDITIONAL FEE
X$ 9=		OR	X$18=	
X40=		OR	X80=	
+135=		OR	+270=	
TOTAL ADDIT. FEE		OR	TOTAL ADDIT. FEE	

4-18-05

AMENDMENT B

	(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA
Total	* 18	Minus	** 58	= –
Independent	* 2	Minus	*** 12	=
FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM				☐

SMALL ENTITY RATE	ADDITIONAL FEE	OR	OTHER THAN SMALL ENTITY RATE	ADDITIONAL FEE
X$ 9=		OR	X$18=	
X40=		OR	X80=	
+135=		OR	+270=	
TOTAL ADDIT. FEE		OR	TOTAL ADDIT. FEE	

AMENDMENT C

	(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA
Total	*	Minus	**	=
Independent	*	Minus	*** 11	=
FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM				☐

SMALL ENTITY RATE	ADDITIONAL FEE	OR	OTHER THAN SMALL ENTITY RATE	ADDITIONAL FEE
X$ 9=		OR	X$18=	
X40=		OR	X80=	
+135=		OR	+270=	
TOTAL ADDIT. FEE		OR	TOTAL ADDIT. FEE	

* If the entry in column 1 is less than the entry in column 2, write "0" in column 3.
** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 20, enter "20."
*** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 3, enter "3."
The "Highest Number Previously Paid For" (Total or Independent) is the highest number found in the appropriate box in column 1.

FORM PTO-875

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ATTORNEY DOCKET NO. TB 104IA CA/ 1915/13971US04

IN THE UNITED STATES
PATENT AND TRADEMARK OFFICE

Applicants: Grooms, James, *et al.* U.S. Serial No.: 09/905,683 Filed: July 13, 2001 For: "MULTI-COMPONENT CORTICAL BONE ASSEMBLED IMPLANT" (AS AMENDED) Group Art Unit: 3738 Examiner: Bruce Edward Snow	CERTIFICATE OF MAILING I hereby certify that this paper (and all papers referred to herein) is being deposited with the United States Postal Service as first class mail, postage prepaid, in an envelope addressed to: Mail Stop AF, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on: December 19, 2005 Donald J. Pochopien Registration No. 32,167 Attorney for Applicants

REQUEST FOR CONTINUED EXAMINATION UNDER 37 C.F.R. § 1.114

Mail Stop AF
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

In response to the Official Action of 06/17/05, for which a Response was due 09/17/05, now extended three (3) months to 12/19/05 (12/17/05 being a Saturday), the Applicants hereby request continued examination of the above identified application under 37 C.F.R. § 1.114 and in support of this request, Applicants cofiled documents authorize the Assistant Commissioner to charge the associated filing fee ($790.00) under 37 C.F.R. §17(e) to Deposit Account No. 13-0017 in the name of McAndrews, Held & Malloy, Ltd.

Applicants also cofile with this request an amendment and response to the prior bases for rejection.

Respectfully submitted,

McANDREWS, HELD & MALLOY, LTD.

By: ______________________

Donald J. Pochopien, Ph.D.
Registration No. 32,167
Attorney for Applicants
500 West Madison Street
Suite 3400
Chicago, Illinois 60661
(312) 775-8133

Dated: December 19, 2005
J:\open\DJP\Regeneration Technologies\13971US04\13971US04 RCE.doc

ATTORNEY DOCKET NO. TB 104IA CA/ 1915/13971US04

IN THE UNITED STATES
PATENT AND TRADEMARK OFFICE

Applicants:
Grooms, James, *et al.*

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For: "MULTI-COMPONENT CORTICAL BONE ASSEMBLED IMPLANT" (AS AMENDED)

Group Art Unit: 3738

Examiner: Bruce Edward Snow

CERTIFICATE OF MAILING

I hereby certify that this paper (and all papers referred to herein) is being deposited with the United States Postal Service as first class mail, postage prepaid, in an envelope addressed to: Mail Stop AF, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on:

December 19, 2005

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AMENDMENT AND RESPONSE

Mail Stop AF
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Sir:

In response to the Official Action of 06/17/05, for which a Response was due 09/17/05, now extended three (3) months to 12/19/05 (12/17/05 being a Saturday), the Applicants supplement their Request for Continued Examination under 37 C.F.R. § 1.114 by cofiling this Amendment and Response, addressing all prior bases for rejection:

Amendment to the Claims:

Please substitute the following listing of the claims for all prior listings of the claims:

Claims 1-110 (Cancelled)

111. (Currently amended) An assembled bone implant suitable for implantation into a patient comprising:

a first cortical bone portion;

a second cortical bone portion;

said first cortical bone portion and said second cortical bone portion having one or more circular through holes sized and positioned for receiving one or more retention pins for connecting said first cortical bone portion to said second cortical bone portion; and

one or more retention pins of appropriate diameter for ~~fitting said through holes and~~ connecting said first cortical bone portion to said second cortical bone portion ~~to form~~ and forming said assembled bone implant as a unitary body outside of said patient~~, said assembled bone implant being suitable for implantation into said patient~~.

112. (Previously presented) The assembled bone implant of claim 113, wherein said first cortical bone portion and said second cortical bone portion each have a D shape.

113. (Previously presented) The assembled bone implant of claim 111, wherein said first cortical bone portion is stacked over said second cortical bone portion.

114. (Previously presented) The assembled implant of claim 112, wherein said retention pin is selected from the group consisting of cortical bone, a bioabsorbable synthetic polymer and titanium.

115. (Previously presented) The assembled implant of claim 114, wherein said

retention pin is cortical bone.

116. (Previously presented) The assembled implant of claim 111, wherein said first cortical bone portion is a mirror image of said second cortical bone portion.

117. (Previously presented) The assembled implant of claim 112, wherein the implant has a beveled edge of defined radius.

118. (Currently amended) The assembled implant of claim ~~111~~ 115, wherein said first cortical bone portion and said second cortical bone portion are in a stacked position relative to one another.

119. (Cancelled)

120. (Previously presented) The assembled implant of claim 112, wherein said first cortical bone portion and said second cortical bone portion are allograft bone.

121. (Previously presented) The assembled implant of claim 112, sized and shaped in the form of a cervical implant.

122. (Previously presented) The assembled implant of claim 112, having a height between 7 and 14 mm.

123. (Previously presented) The assembled implant of claim 111, wherein said one or more retention pins comprise a cancellous bone portion.

124. (Previously presented) The assembled implant of claim 123, wherein said cancellous bone portion is treated with a bone morphogenetic protein (BMP).

125. (Previously presented) The assembled implant of claim 112, wherein said

implant has two opposing surfaces that are inscribed with teeth.

126. (Previously presented) A D-shaped assembled bone implant for implantation into a patient comprising:

a first cortical bone portion having a D shape; and

a second cortical bone portion having a D-shape;

said first cortical bone portion and said second cortical bone portion being superimposed to form D-shaped implant having the combined thickness of said first cortical bone portion and said second cortical bone portion, said D-shaped implant having a through-hole sized and positioned for receiving a retention pin for retaining said first cortical bone portion to said second cortical bone portion in stacked formation.

127. (Previously presented) The assembled implant of claim 126, wherein said retention pin is a cortical bone pin.

128. (Previously presented) The assembled implant of claim 126, wherein said retention pin is a cancellous bone portion is treated with a bone morphogenetic protein.

129. (New) An assembled bone implant suitable for implantation into a patient comprising:

a first cortical bone portion of allograft bone;

a second cortical bone portion of allograft bone;

said first cortical bone portion and said second cortical bone portion having one or more through holes sized and aligned for receiving one or more retention pins for connecting said first cortical bone portion to said second cortical bone portion; and

one or more retention pins of appropriate diameter for connecting said first cortical bone portion to said second cortical bone portion and forming said assembled bone implant outside the body of a patient as a unitary body suitable for implantation into a patient.

130. (New) The assembled bone implant of claim 129, wherein said first cortical bone portion and said second cortical bone portion each have a D shape.

131. (New) The assembled bone implant of claim 129, wherein said first cortical bone portion is stacked over said second cortical bone portion.

132. (New) The assembled implant of claim 130, wherein said retention pin is selected from the group consisting of cortical bone, a bioabsorbable synthetic polymer and titanium.

133. (New) The assembled implant of claim 132, wherein said retention pin is cortical bone.

134. (New) The assembled implant of claim 133, wherein said first cortical bone portion is a mirror image of said second cortical bone portion.

135. (New) The assembled implant of claim 134, wherein the implant has a beveled edge of defined radius.

136. (New) The assembled implant of claim 133, wherein said first cortical bone portion and said second cortical bone portion are in a stacked position relative to one another.

REMARKS

The amendments to the claims do not add new matter. Claim 111 has been amended to recite that the "assembled implant is "suitable for implantation into a patient." Support for the "assembled implant" being "suitable for implantation into a patient" is found throughout the specification, including at page 4 line 19 (". . .shipment to physicians for use in implantation procedures."). Claim 111 has also been amended to recite that the through holes are "circular." Support for the through holes being "circular" is shown in FIG. 7A as circular holes 701, 702, 703 and 704; and is found in the specification at page 19, line 4 ("holes 701-704 have been drilled"). Accordingly, the amendments to claim 111 would not add new matter.

New claims 129-136 parallel claims 111-118 with the exception that claim 129 recites that both cortical bone portions are "allograft" bone. Support for the bone being "allograft" is found in the specification at page 3, line 5.

For all these reasons, the amendments to the claims do not add new matter.

Summary of the Bases for Rejection/Objection

Claims 111-118 and 120-128 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting over all claims in USSN 10/375,540.

Claims 111-118 and 120-123 are rejected under 35 U.S.C. § 102(b) over Albee, Scientific American, "Bone Surgery with Machine Tools," 154(4) 178-181 (1936).

Claims 111-118 and 120-128 are rejected under 35 U.S.C. § 103(a) over U.S. Pat. 5,989,289 (Coates) in view of EP 517030 (Siebels).

Claims 111-118 and 120-128 are rejected under 35 U.S.C. § 103(a) over U.S. Pat. 5,192,327 (Brantigan) in view of U.S. Pat. 5,989,289 (Coates).

The Applicants will answer each of these bases for objection in Sections I-IV, respectively which follow.

I. Obviousness-type Double Patenting

Claims 111-118 and 120-128 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting over all claims in co-pending sister application USSN 10/375,540. No claims have been deemed allowable in the present application. Applicants will consider cofiling an appropriate terminal disclaimer at such time as claims are determined to be allowable.

II. 35 U.S.C. § 102(b) over Albee

Claims 111-118, 120-123 and 126-127 are rejected under 35 U.S.C. § 102(b) over Albee, Scientific American, "Bone Surgery with Machine Tools," 154(4) 178-181 (1936). In response to the Official Action of 12/15/04, the Applicants amended claim 111 to recite "An assembled bone implant suitable for implantation into a patient. . ." The Patent Office responded stating "Regarding the language 'suitable for implantation into a patient' found in the preamble, it is not clear if that **limitation** breathes any life and meaning into the claim." [Official Action at page 2; emphasis added in bold.] The Patent Office acknowledges that the words are a "limitation" but then misconstrues what is meant by "breathing life and meaning" into a claim. The test is whether the language in the preamble is merely a preambular statement of purpose, which is given no weight as a limitation, or is necessary to give life and meaning to the claim. The courts have recognized that when the body of a claim contains an express reference back to the antecedent recitation in the preamble, then that recitation is incorporated by reference into the claim. See Thus, in the body of claim 111, the reference back to "the assembled bone implant" means "the assembled bone implant suitable for implantation into a patient." However, at the cost of being redundant, the Applicants have amended the last phrase in the body of claim 111 to recite "said assembled bone implant being suitable for implantation into said patient." Accordingly, this recitation is now an element of claim 111.

Citing to "all figures, specifically figures 10-12 and 15," the Patent Office

states that Albee discloses the elements of claim 111, prior to the amendments herein. [Official Action at page 4.]

> a first cortical bone portion;
>
> a second cortical bone portion;
>
> said first cortical bone portion and said second cortical bone portion having one or more circular through holes sized and positioned for receiving one or more retention pins for connecting said first cortical bone portion to said second cortical bone portion; and
>
> one or more retention pins of appropriate diameter for fitting said through holes and connecting said first cortical bone portion to said second cortical bone portion ~~to form~~ and forming said assembled bone implant as a unitary body outside of said patient, said assembled bone implant being suitable for implantation into said patient.
>
> [Claim 111 as amended herein.]

The Applicants respectfully disagree.

Albee only has Figures 1-6. However, when the Patent Office is referring to FIGS. 10-12 and 15 of Albee, it is believed that the Patent Office is referring to the subparts in Figure 3 of Albee, which has subparts 1-15 therein. If the Applicants are wrong, then the Applicants request a corrected Official Action wherein the Figures are properly designated and the Applicants are not required to speculate.

1. Albee Does Not Disclose Implants That Exist in Assembled Form Outside the Body

As an initial matter, Applicants point out that the applicants are claiming an "assembled" implant that exists in "assembled" form outside the body (in vitro) and that is "suitable for implantation in the patient's body." They are "off the shelf" assembled devices (i.e., devices in the mechanical sense). In marked contrast, all of the grafts

disclosed in Figure 3 of Albee fail to exist in assembled form outside the body. There is no "assembled" implant disclosed in Albee that exists outside the body, and that in assembled form is "suitable for implantation into a patient." Rather, Albee discloses shaping a single piece of the patient's own (autograft) bone to fit between two opposing segments of the patient's living in vivo bone to bridge a size gap or hold the two opposing living segments in appropriate juxtaposition. The resulting assembled structure is not an "assembled implant" it is a reconstructed area. Moreover, whatever is assembled in a patient in Albee exists only in vivo, and is not "suitable for implantation in a patient" because it would require removing the patients' own bones and the interconnecting piece so that they exist in vitro as an assembled implant. Thus, at no time does Albee ever teach an "assembled implant" suitable for implantation in the body. Consistent with this interpretation, the Applicants have expanded the body of independent claim 111 to recite that the already "assembled implant" is "suitable for implantation in a patient."

Throughout Albee's disclosure, Albee discloses that the single piece of bone is removed from one portion of the patient as living tissue, is shaped and then transferred as a single (living) piece to the living bone in the body of the patient:

> The **graft lives** if it is supplied sufficiently early and in quantity with blood from the host.
>
> [Albee at page 180, col. 1; emphasis added in bold.]
>
> * * *
>
> The **vascular channel**, especially the **capillaries**, in the **graft** and host bone unite.
>
> [Albee at page 180, col. 3; emphasis added in bold.]
>
> * * *
>
> **Compression may kill bone cells**, either **in graft** or host tissues, or close blood vessels that should otherwise bring nourishment to the **living graft cells**.

[Albee at page 181, col.2; emphasis added in bold.]

* * *

> The successful **living bone-graft** is based upon a tripod of exacting conditions and environment as to mechanics, physiology and biology.
>
> [Albee at page 181, col.2; emphasis added in bold.]

Thus, at no time does Albee disclose an isolated "assembled implant" that is suitable for implantation in a patient. Further, drawing 7 in Figure 3 of Albee is the only drawing that discloses the use of more than one isolated piece of bone. It shows the use of two pieces of bone that would be connected in the living body sequentially and never as "an assembled implant."

Albee describes subparts 11 and 12 of Figure 3 as follows "Numbers 11 and 12 are keyed-in tension members in **broken knee caps** which **will not join**." [Albee at the caption to Figure 3; emphasis added in bold.] The broken knee caps of subparts 11 and 12 of Figure 3 are "**broken**" not disconnected from the respective tendons. They "**will not join**" because they are connected to their respective tendons which are pulling them in opposite directions. For simplicity, the tendons were not shown. However, as "broken" knee caps, they exist inside the body of the patient, connected by their respective tendons to the remainder of the body. At no time do they exist outside the body so as to satisfy the limitation to an assembled implant "forming a unitary body outside the patient suitable for implantation into the patient." For all these reasons, claims 111-118 and 120-123 would not be anticipated by Albee.

2. FIGS. 11 and 12 of Albee (Subparts 11 and 12 of Fig. 3) fail to show "D" shaped bone portions

Claim 112 recites that "said first cortical bone portion and said second cortical bone portion each have a D shape." Claims 114-115 and 117-118 incorporate this limitation by reference thereto. The Patent Office contends that in figures 11-12, "Albee

teaches superimposed cortical bone portions each having a **D-shape** having a through hole with [sic "which"] receives the I shaped pin interpreted as having the **appropriate diameter**." [Official Action at page 4.] The Applicants respectfully disagree.

One skilled in the art, and even a child, understands that the letter "D" is a closed loop. In contrast, the letter "C" is an open loop. The knee cap fragments shown in subparts 11 and 12 of Figure 3 of Albee are open loops and thus at best "C" shaped not "D" shaped. For this reason, claims 112, 114-115 and 117-118 would not be anticipated by Albee.

Separately, the I-shaped insert of subpart 11 of Albee and the X-shaped tenon insert of subpart 12 of Figure 3 of Albee do not have a "diameter." However, the Patent Office has "interpreted" the I-shape and the X-shape inserts of Albee as "having the appropriate diameter." [Official Action at page 4.] The Applicants request that the Patent Office point out where the "diameter" occurs, since a diameter is by definition associated only with circular or spherical objects.

> diameter- the straight line passing through the center of a **circle, sphere**, etc., from one side to the other.
>
> [Exhibit B: Webster's New World Dictionary, Second College Edition, Ed, Guralnik, Prentice Hall Press, Cleveland Ohio 1986 at page 389; emphasis added in bold.]

In contrast, the I-shaped and X-shaped inserts of subparts 11 and 12 of figure 3 are substantially planar and have straight line edges. For these reasons also, claims 111-118 and 120-123 would not be anticipated by Albee.

3. FIGS. 11 and 12 of Albee (Subparts 11 and 12 of Fig. 3) fail to show a through hole in the bone portions

The Patent Office next alleges that in figures 11 and 12, "Albee teaches superimposed first and second cortical bone portions each having a D-shape having a **through hole** with [sic "which"] receives the I shaped pin interpreted as having the appropriate diameter." [Official Action at page 4; emphasis added in bold.] One skilled in

the art, and even a child, knows that a "hole" by definition is surrounded by the material into which it is placed. For example, it is elementary that a donut hole is surrounded by the rest of the donut. If it looked as in subparts 11 or 12 of Albee, one skilled in the art would know that someone took a bite out of their donut. Likewise, a button hole on a shirt is surrounded by the rest of the shirt. If it looked like subparts 11 and 12 of Albee it would be a **notch** and not a **hole**, and it would cease to function. Finally, when a golfer hits a "hole in one" the "hole" is surrounded by the green. It is not a notch in the side of a hill. By comparison, a "notch" is defined as a cut or indentation in a surface:

> **notch** a concave or V-shaped **cut or indentation in an edge** or across a surface.
>
> [Exhibit B: Webster's New World Dictionary, Second College Edition, Ed, Guralnik, Prentice Hall Press, Cleveland Ohio 1986 at page 973; emphasis added in bold.]

Referring back to subparts 11 and 12 of Figure 3 of Albee, it is clear that the broken knee cap fragments have a "notch" in their adjoining **edges** and not a hole that is otherwise surrounded by kneecap. For this reason also, claims 111-118 and 120-123 would not be anticipated by Albee.

4. Half of the Items disclosed in Figure 3 of Albee are a cabinet maker's "joinery" which Albee presents for "analogy"

Addressing the merits of the rejection, in Figure 3 of Albee, each of subparts 1a, 2b, 3a, 4a, 5a, 6a, 7a, 7b, 8a, 9a, 10a 11a, 11b, 12a, 13a, and 15 are cabinetry joints (i.e., "joinery elements"), which Albee cites to as analogy, and not actual implants in a patient:

> The fine joinery element in bone surgery-a group of **self evident analogies**.
>
> [Albee at caption to Figure 3; emphasis added in bold.]
>
> * * *
>
> For help with the mechanical problem, **one must go to the joiner**

> and **study** his various forms of **mortise** and how he selects each according to the mechanical demands of the situation (Figure 3).
>
> [Albee at page 180, col. 2; emphasis added in bold.]

In Figure 3, only subparts 1, 2, 2a, 3, 4, 5, 6, 8, 9, 10, 11, 12, 13, and 14 show a bone repair using a single isolated and shaped piece of living bone to connect or bridge the gap between adjacent pieces of bone in vivo. As discussed above, subpart 7 of Figure 3 discloses the use of two separate pieces of bone that are connected (by the disclosed mortise and tenon joint) only when attached to the body (in vivo). Thus, at no time does Albee teach or suggest an "assembled implant suitable for implantation in a patient."

For all these reason, Albee would not be anticipatory of any of claims 111-118, (withdrawn claim 119), 120-123, and 126-127 of the present invention. Albee also would not be anticipatory of any of newly added claims 129-136 because they include the same limitations.

III. 35 U.S.C. § 103(a), Coates over Siebels

Claims 111-118 and 120-128 are rejected under 35 U.S.C. § 103(a) over U.S. Pat. 5,989,289 (Coates) in view of EP 517030 (Siebels). According to the Patent Office, "[r]eferring to all figures, Coates teaches a D-shaped cortical bone spinal implant. . . ." [Official Action at pages 5 citing to Coates at col. 11, lines 42 et seq.] The Patent Office admits that "**Coates et al fails to teach said implant can comprise a first and second portion capable of being connected by a pin**." [Official Action at page 5; emphasis added in bold.] To make up for this deficiency, the Patent Office cites to Siebels, stating that Siebels discloses "a spinal implant and teaches stacking portions 11 of the implant and connecting said portions with pins 17." [Official Action at page 4.] The Patent Office then concludes that "[i]t would have been obvious to one skilled in the art to have utilized the teachings of Siebels to stack and connect the individual implant portions with the D-shaped cortical bone implant of Coates wherein multiple portions could be stacked and connected by at least one pin in corresponding through holes to adjustably

build the implant to a desired height (thickness) to best fill the disk space as desired by the surgeon." [Official Action at page 5.] The Applicants respectfully disagree.

In order for an invention to be obvious, "Both the suggestion and the expectation of success must be founded in the prior art, not in applicant's disclosure." Amgen v. Chugai, 18 USPQ2d 1016, 1022 (Fed. Cir. 1991); emphasis added in bold. In the present case, Siebels discloses that it was an object of their invention to make an implant that can "easily be manufactured for a multiplicity of overall dimensions:"

> Therefore, the objective to develop an implant of the kind mentioned at the outset, which can rapidly be implanted and which - from the standpoint of manufacturing engineering - can also **easily be manufactured** for a **multiplicity of overall dimensions**, forms the basis of the [proposed] invention.
>
> In accordance with the invention, the set objective is achieved with the help of the features, cited in claim 1.
>
> [English Translation of Siebels at page 2, line 20 to page 3, line 1; emphasis added in bold.]

To achieve the "ease" of manufacturing, Siebels relies upon cutting discs out of "prefabricated solid or hollow strand." [English Translation of Siebels at page 3, line 7.] Specifically, Siebels discloses that this mode of manufacturing, comprising cutting appropriately sized strands made of "fiber reinforced plastic" provides for "manufacturing" in a "extraordinarily easy way":

> The disk-shaped implant is preferably made of fiber-reinforced plastic [FRP]. In accordance with a preferred embodiment of the invention, in order to produce a single-piece implant, the disk is cut out of a hollow strand, which consists of a multiple number of braiding layers [plaiting layers]. The braiding layers, are wound up one after another on a correspondingly shaped mandrel [arbor], preferably on a mandrel, having rectangular cross-section and rounded corners, directly in a braiding machine. The disks are cut off with the desired height, which can vary over the disk. Implants of this kind are characterized in that they can be manufactured in an **extraordinarily easy way**, in which the **fiber orientation** equally **imparts an optimal rigidity** and **strength** to

the implant.

> [English Translation of Siebels at page 3, line 22 to page 4, line 9; emphasis added in bold.]

Thus, the heart of Siebel's invention is a prefabricated template that can be cut into directly useable slices to produce an implant "in an extraordinarily easy way." By use of the adjective "extraordinary," Siebels meant to convey that the disclosed process of manufacturing plastic implants was not just "easy" but "extraordinarily easy."

In addition, the above quote from Siebels teaches that "fiber orientation" is important because it "imparts an optimal rigidity." The word "optimal" is a superlative and means "most favorable or desirable; best; optimum." [Exhibit B: Webster's New World Dictionary, Second College Edition, Ed. Guralnik, Prentice Hall Press, 1986 at page 999; emphasis added in bold.] Thus, fiber orientation is a necessary element in the material used by Siebels to "impart optimal rigidity."

In contrast to the "extraordinarily easy" method of manufacturing disclosed in Siebels (that provides for an implant having "optimal rigidity"), Coates discloses that "developing an implant having the biomechanical properties of metal and the biological properties of bone without the disadvantages of either has been extremely difficult or impossible." [Coates at col. 3, lines 35-39.] By this statement, Coates teaches that as of its filing date (October 1995), cortical bone was not a "traditional orthopedic implant material" for spinal implants. It was considered "extremely difficult or impossible" to provide an implant that had the benefits of both bone and metal without their undesired properties. The words "extremely difficult or impossible" are superlatives related to difficulty or impossibility. Given this "extremely difficult or impossible" setting, one would not have been motivated to substitute the cortical bone of Coates for the preformed plastic of Siebels. Given the art recognized extreme difficulty or impossibility, one skilled in the art would have even been less motivated to build an implant from little pieces of bone held together with pins, and there would not have been a reasonable expectation of success that the Applicants' would have been able to make implants for use in the spine from assembled pieces of cortical bone. See Amgen v. Chugai, 18 USPQ2d at 1022. For

these reasons, claims 111-118 and 120-128 would not have been obvious under 35 U.S.C. § 103(a) over U.S. Pat. 5,192,327 (Brantigan) in view of U.S. Pat. 5,989,289 (Coates).

In response to the Applicants' arguments, the Patent Office contends that "Coates specifically states that the implant of Brantigan is flawed because the materials used (including metals) of Brantigan are too stiff which causes stress shielding, etc." [Official Action at page 3.] However, as correctly pointed out in the very next sentence of the Official Action, Coates remarks are limited to metals:

> Coates in the very next paragraph teaches that bone as an implant material "**avoid[s] the disadvantages of metal implants**": see column 2, lines 49 et seq.
>
> [Official Action at page 3, quoting Coates; emphasis added in bold.]

However, Siebels' implants are not limited to metals. Siebel also teaches that its **preferred embodiment** is not a metal either, but rather is a fiber (e.g., graphite) reinforced plastic (as on the stealth bomber), which does not have the disadvantages associated with metal such as stress-shielding, or radio-opaqueness:

> The disk-shaped implant is **preferably** made of **fiber-reinforced plastic [FRP]**. In accordance with a **preferred embodiment** of the invention, in order to produce a single-piece implant, the disk is cut out of a hollow strand, which consists of a multiple number of braiding layers [plaiting layers]. The braiding layers, are wound up one after another on a correspondingly shaped mandrel [arbor], preferably on a mandrel, having rectangular cross-section and rounded corners, directly in a braiding machine. The disks are cut off with the desired height, which can vary over the disk. Implants of this kind are characterized in that they can be manufactured in an **extraordinarily easy way,** in which the **fiber orientation** equally **imparts an optimal rigidity** and **strength** to the implant.
>
> [English Translation of Siebels at page 3, line 22 to page 4, line 9; emphasis added in bold.]

See also Brantigan at [Brantigan at col. 3, lines 9-12 ("The **implants** are **preferably** made

of **radiolucent** material such as **carbon fiber reinforced polymers**. . . .").] Coates does not address or overcome the advantages associated with fiber reinforced plastic, so as to motivate one skilled in the art to disregard the advantages associated with Siebels' ease of construction and stated advantages relative to bone which required complex machining and was totally untested in stacked formation. In fact, Siebels states that this preferred embodiment imparts "**optimal rigidity**." Coates never addressed this preferred embodiment which Siebels also disclosed was "preferred" over metal.

For this reason and all of the above reasons, the combination of Coates and Siebels would have failed to render obvious claims 111-118 and 120-128 at the time that the Applicants' invention was made.

IV. 35 U.S.C. § 103(a), Brantigan over Coates

Claims 111-118 and 120-128 are rejected under 35 U.S.C. § 103(a) over U.S. Pat. 5,192,327 (Brantigan) in view of U.S. Pat. 5,989,289 (Coates). According to the Patent Office, Figures 2 and 5 of Brantigan teach a D-shaped implant comprising:

> a first portion 21;
> a second portion 21;
> said first portion and said second portion having one or more through holes 24 sized and positioned for receiving one or more retention pins 15 for connecting said first ~~cortical bone~~ [sic] portion to said second ~~cortical bone~~ [sic] portion; and
> one or more retention pins of appropriate diameter for connecting said first ~~cortical bone~~ [sic] portion to said second ~~cortical bone~~ [sic] portion to form said assembled bone implant unitary body.
>
> [Official Action at pages 6-7; strikeout corrections added.]

The above statement from the Patent Office is incorrect on its face because Brantigan never discloses any component or "portion" of an implant that is made of "**cortical bone**." In a

later sentence of the Official Action, the Patent Office acknowledges that "**Brantigan fails to teach that the first and second portions are cortical bone.**" [Official Action at page 7; emphasis added in bold.] Moreover, in the Patent Office's argument quoted above, the terms "said first cortical bone portion" and "said second cortical bone portion" lack antecedent basis and the resulting argument is indefinite. As a result, it is difficult to know what the Patent Office is contending.

1. When Brantigan is Properly interpreted, there is no Motivation to substitute the cortical bone of Coates for the "fiber reinforced plastic" in the implants of Brantigan

The Patent Office next contends that "[i]t would have been obvious to one of ordinary skill in the art to have used cortical bone which is a traditional, orthopaedic implant material as taught by Coates for any of the elements of Brantigan because '5,192,327 to Brantigan teach hollow metal cage structures. Unfortunately, due to the stiffness of the material, some metal implants may stress shield the bone graft, increasing the time required for fusion or causing the bone graft to resorb inside the cage. Subsidence, or sinking of the device into bone, may also occur when metal implants are implanted between vertebrae if fusion is delayed. Metal devices are also foreign bodies which can never be fully incorporated into the fusion mass.'" [Official Action at page 7.] The Applicants respectfully submit that Coates misinterprets Brantigan.

Specifically, Coates teaches away from the use of metals, just as Brantigan teaches away from metals. As a matter of law, "A prior art reference may be considered to **teach away** when 'a person of ordinary skill, upon reading the reference, would be discouraged from following the path set out in the reference, or **would be led in a direction divergent from the path taken by the applicant.**" *Monarch Knitting v. Sulzer*, 45 USPQ2d 1977, 1984 (Fed. Cir. 1998) (emphasis added in bold.). In particular, Brantigan teaches that fiber reinforced plastics are "preferred" over metals:

> The **implants** are **preferably** made of radiolucent material such as **carbon fiber reinforced polymers** known commercially as

"Peek", (polyetherether ketone) or "Ultrapek" (polyether ketone, ether ketone, ketone). Alternately, polycarbonate, polypropylene, polyethylene and polysulfone type plastics material filled with glass or carbon fibers can be used. Such materials are supplied by ICI Industries of Wilmington, Del.; Fiber-Rite Corporation of Winona, Minn. or BASF Corporation.

[Brantigan at col. 3, lines 9-18; emphasis added in bold.]

In fact, other than in Brantigan's Abstract, Brantigan never mentions the five specific metals (that are the traditional orthopaedic materials). Thus, Brantigan taught away from the use of metals by teaching that a preference for fiber reinforced plastic (as also used in Siebels), over metals. Coates never addressed Brantigan's primary disclosure, which is directed to the use of fiber reinforced plastics which is the heart of Brantigan's invention. Further, Coates' arguments at col. 2, lines 54-65 regarding the stress shielding caused by the stiffness of titanium alloys (114Gpa) and 316L stainless steel (193Gpa) versus cortical bone (about 17Gpa) do not apply to the carbon fiber reinforced PEEK (17.8 Gpa), carbon fiber reinforced polyetherketoneetherketoneketone (PEKEKEKK) (6.9-29.4 Gpa) or carbon fiber reinforced polycarbonate (4.1-21.4 Gpa) as disclosed in Brantigan at col. 3, lines 9-13. [See Exhibit A: from www.matweb.com at page 2, line 10 "Flexural modulus".] These fiber reinforced polymers have a stiffness (e.g. 17.8 Gpa) that is analogous to the stiffness cortical bone (about 17 Gpa) and substantially less than the stiffness (114-193 Gpa) of the recited metals. [These arguments apply with equal force regarding the carbon fiber reinforced plastic of Siebels in Section III supra.] Thus, the fiber reinforced plastics of Brantigan do not have the disadvantage of "stress shielding" that is associated with metals. Further, the fiber reinforced plastics of Brantigan (and Siebel) offer yet another advantage of cortical bone because, unlike metals, both are transparent to X-rays. (See Coates at col. 2, lines 62-65 ("Moreover, bone as an implant also allows excellent postoperative imaging because it does not cause scattering like metallic implants on CT or MRI imaging."); Brantigan at col. 3, lines 9-10 ("The implants are preferably made of radiolucent material such as carbon fiber reinforced polymers known commercially as 'Peek' (polyetheretherketone) or 'ultrapeek' (polyether ketone, ether ketone, ketone)"); and Siebel

– Eng translation at page 6, 2nd full ¶ ("Preferably, the disks are made of a carbon-fiber reinforced plastic (CFP) whereby the anchoring means - according to the design of the implant - can consist of the same, or another material. The manufacturing of the entire implant of CFP has the advantage that the implant does not bring about any scattering of rays, so that the spinal column and the adjacent biological tissue can also be examined after the implantation of a spinal-column replacement with the help of all image-producing methods (CT, MR);" emphasis added in bold). Thus, Coates misstates the teaching in Brantigan, which is not limited to metal implants, but rather is directed as its preferred embodiment to implants made from "carbon fiber reinforced plastic." Hence, one skilled in the art, upon reading both Coates and Brantigan, would not have been motivated to substitute the cortical bone of Coates for the fiber reinforced plastic of Brantigan, which Coates never discussed.

2. There is No Suggestion to Substitute Cortical Bone for Plastic or a Reasonable Expectation of Success

The Patent Office next contends that it "would have been obvious to one having ordinary skill in the art to have utilized cortical bone which is a traditional orthopedic implant material as taught by Coates for any of the elements of Brantigan." [Official Action at page 7.] The Applicants respectfully disagree.

In order for an invention to be obvious, "Both the suggestion and the expectation of success must be founded in the prior art, not in applicant's disclosure." *Amgen v. Chugai*, 18 USPQ2d 1016, 1022 (Fed. Cir. 1991); emphasis added in bold. In the present case, at the time of Brantigan's 1991 filing date, Brantigan expressly teaches that the traditional orthopedic materials for spinal implants were "nickel, chromium, cobalt, stainless steel or titanium." [Brantigan at the Abstract, last two lines.] At the time of Coates' earliest claimed filing date (October 1995), Coates teaches that "developing an implant **having the biomechanical properties of metal** and the **biological properties of bone without the disadvantages of either** has been **extremely difficult or impossible.**" [Coates at col. 3, lines 35-39; emphasis added in bold.] Thus, at the filing date (October

1995) of Coates, Coates teaches that cortical bone was not a "traditional orthopedic implant material" for spinal implants. It was considered "extremely difficult or impossible" to provide an implant that had the benefits of both bone and metal without their undesired properties. Given this "extremely difficult or impossible" setting, there would not have been a reasonable expectation of success that the Applicants' would have been able to make implants for use in the spine from assembled pieces of cortical bone. However, Coates comments, while specifically addressing metal implants, never addressed the graphite reinforced implants of Brantigan which even Brantigan preferred over metal and which had the same modulus of flexibility as bone (thereby overcoming stress shielding of metal) and which were radiolucent (thereby overcoming the radio-opacity of metal) and which were easy to make in any size. For these reasons, claims 111-118 and 120-128 would not have been obvious under 35 U.S.C. § 103(a) over U.S. Pat. 5,989,289 (Coates) in view of EP 517030 (Siebels)..

3. Even if Combined, the Combination of Coates and Brantigan would not make a prima facie case of Obviousness

Independent claim 111 of the Applicants' invention includes as elements the following:

a first cortical bone portion;

a second cortical bone portion;

said first cortical bone portion and said second cortical bone portion having one or more **circular through holes** sized and positioned for receiving one or more **retention pins** for connecting said first cortical bone portion to said second cortical bone portion; and

> one or more **retention pins of appropriate diameter** for fitting said through holes and connecting said first cortical bone portion to said second cortical bone portion ~~to form~~ and forming said assembled bone implant as a unitary body outside of said patient, said assembled bone implant being suitable for implantation into

said patient.

[Claim 111 as amended herein; emphasis added in bold.]

Thus, one of the elements of Applicant's claim 111 is a "retention pin of appropriate diameter." Independent claim 120 also recites the same term "retention pin". One skilled in the art recognizes that the ordinary meaning of the term "diameter" means that the retention pin has a substantially circular cross section. This is also seen in the circular "through holes" 701-704 of Applicants' FIG. 7A. In contrast, Brantigan does not teach or suggest the use of any "pins" of any "diameter." Rather, Brantigan discloses the use of a "rectangular connecting bar" of FIG. 3 to interconnect a plurality of D-shaped plastic devices of FIG. 2 in stacked array as shown in FIG. 5 of Brantigan:

> These grooves are provided for mounting a rectangular connecting bar 15 shown in FIG. 3. This **bar** 15 has **flat side faces** 15a, rounded side edges 15b to **snugly fit the grooves** 14. . . .
>
> [Brantigan at col. 4, lines 25-28; emphasis added in bold.]

The Patent Office has acknowledged that Coates "fails to teach said implant can comprise a first and second portion capable of being connected by a pin." [Official Action at page 4.] Thus, the combination of Coates and Brantigan fail to teach or suggest an essential element of claim 111, i.e., a "retention pin" having a rounded cross section of "appropriate diameter" for the "**circular** through hole." Likewise independent claim 126 also recites as an element a "retention pin." Claims 112-118, 120-125 and 127-128, which ultimately depend from claims 111 and 126, would also incorporate the limitation to a "retention pin" and "circular through hole" by reference thereto. Accordingly, claims 111-118 and 120-128 would not have been obvious over the combination of Coates and Brantigan.

CONCLUSION

The provisional rejection of all claims of this restricted invention for double patenting over all claims of a separately restricted sister application will be address at such time as claims in one of the applications has been allowed. The rejection of claim 117 under 35 U.S.C. § 112, second paragraph, for indefiniteness has been rendered moot by amendment herein. The rejection of claims 111-118, 120-123 and 126-127 under 35 U.S.C. § 102(b) over Albee have been rebutted by evidence and arguments herein. The rejection of claims 111-118 and 120-128 under 35 U.S.C. § 103(a) over U.S. Pat. 5,989,289 (Coates) in view of EP 517030 (Siebels) have been rebutted by evidence and arguments herein. Finally, the rejection of claims 111-118 and 120-128 under 35 U.S.C. § 103(a) over U.S. Pat. 5,192,327 (Brantigan) in view of U.S. Pat. 5,989,289 (Coates) have been rebutted by evidence and arguments herein. For the same reasons, these bases for rejection should not apply to parallel claims 129-136 which include the same elements.

The allowance of claims 111-118 and 120-136 is respectfully requested.

Respectfully submitted,

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Dated: December 19, 2005

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		SGL Carbon Group 30% SIGRAFIL C® - filled PEEK	Overview - Polyetherketoneetherketoneketone (PEKEKK), Carbon Fiber Filled	Overview - Polycarbonate, Carbon Fiber Reinforced
Physical				
1	Density (g/cc)	1.4	1.33 - 1.41	1.21 - 1.39
2	Water Absorption (%)	0.17	0.1 - 0.2	0.08 - 0.2
3	Linear Mold Shrinkage (cm/cm)	--	0.0005 - 0.001	0.0005 - 0.0053
4	Linear Mold Shrinkage, Transverse (cm/cm)	--	0.015	--
Mechanical				
5	Hardness, Rockwell R	--	--	118 - 120
6	Tensile Strength, Ultimate (MPa)	218	183 - 269	83 - 200

7	Tensile Strength, Yield (MPa)	--	--	110
8	Elongation at Break (%)	1.6	1.4 - 2.5	1.5 - 8
9	Modulus of Elasticity (GPa)	--	12.4 - 26.2	4.8 - 24.1
10	Flexural Modulus (GPa)	17.8	6.9 - 21.4	4.1 - 21.4
11	Flexural Yield Strength (MPa)	297	270 - 379	124 - 296
12	Compressive Yield Strength (MPa)	--	--	114 - 152
13	Izod Impact, Notched (J/cm)	--	1 - 1.1	0.48 - 1.87
14	Izod Impact, Notched (ISO) (kJ/m²)	9	--	--
15	Izod Impact, Unnotched (J/cm)	--	8 - 9.1	2.94 - 9.5
16	Izod Impact, Unnotched (ISO) (kJ/m²)	43.2	--	--
17	K (wear) Factor	--	5000	--
Electrical				
18	Electrical Resistivity (ohm-cm)	5500	100000	5 - 1e+010
19	Surface Resistance (ohm)	--	--	5 - 1e+010
Thermal				
20	CTE, linear 20°C (µm/m-°C)	--	--	13 - 31
21	Thermal Conductivity (W/m-K)	--	--	0.55 - 0.72
22	Maximum Service Temperature, Air (°C)	--	--	100 - 149
23	Deflection Temperature at 0.46 MPa (66 psi) (°C)	--	--	141 - 151
24	Deflection Temperature at 1.8 MPa (264 psi) (°C)	--	271 - 354	100 - 149

25 Glass Temperature (°C)	--	--	150
26 Flammability, UL94	--	V-0	HB - V-0
Processing			
27 Processing Temperature (°C)	--	--	300 - 318
28 Mold Temperature (°C)	--	--	85 - 121
29 Drying Temperature (°C)	--	--	120
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SECOND COLLEGE EDITION

WEBSTER'S NEW WORLD DICTIONARY

OF THE AMERICAN LANGUAGE

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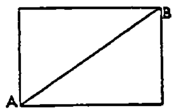
di·ag·o·nal (dī ag′ə n'l) *adj.* [L. *diagonalis* < Gr. *diagōnios* < *dia-*, through + *gōnia*, an angle, corner: for IE. base see KNEE] 1. extending between the vertices of any two nonadjacent angles in a polygonal figure or between any two vertices not in the same face in a polyhedral figure; extending slantingly between opposite corners 2. moving or extending obliquely, esp. at a 45° angle; slanting 3. having slanting markings, lines, etc. —*n.* 1. *a)* a diagonal line or plane *b)* *same as* VIRGULE 2. any diagonal course, row, order, or part 3. cloth woven with diagonal lines; twill —**di·ag′o·nal·ly** *adv.*



DIAGONAL

di·a·gram (dī′ə gram′) *n.* [Gr. *diagramma* < *diagraphein*, to mark out by lines, draw < *dia-*, through, across + *graphein*, to write: see GRAPHIC] 1. a geometrical figure, often used to illustrate a theorem 2. a sketch, drawing, or plan that explains a thing by outlining its parts and their relationships, workings, etc. 3. a chart or graph explaining or illustrating ideas, statistics, etc. —*vt.* **-gramed′** or **-grammed′**, **-gram′ing** or **-gram′ming** to show or represent by a diagram; make a diagram of —**di′a·gram·mat′ic** (-grə mat′ik), **di′a·gram·mat′i·cal** *adj.* —**di′a·gram·mat′i·cal·ly** *adv.*

di·a·ki·ne·sis (dī′ə ki nē′sis) *n.* [ModL. < DIA- + Gr. *kinēsis*, motion: see KINEMATICS] in the meiosis of germ cells, a stage in which the maternal and paternal chromosomes have paired within the nucleus —**di′a·ki·net′ic** (-net′ik) *adj.*

di·al (dī′əl, dīl) *n.* [ME. < ML. *dialis*, daily < L. *dies*, day: see DEITY] 1. a sundial 2. the face of a watch or clock 3. the face of a meter, gauge, compass, etc. on which a pointer or the like indicates an amount, degree, direction, etc. 4. a graduated disk on a radio, or television set, esp. one for tuning in stations or channels ☆5. a rotating disk on a telephone, used in making connections automatically —*vt.*, *vi.* **-aled** or **-alled**, **-al·ing** or **-al·ling** 1. to measure with or as with a dial 2. to show on a dial 3. to tune in (a radio station, television channel, program, etc.) ☆4. to call on a telephone by using a dial

dial. 1. dialect(al) 2. dialectic(al)

di·a·lect (dī′ə lekt′) *n.* [L. *dialectus* < Gr. *dialektos*, discourse, discussion, dialect < *dialegesthai*, to discourse, talk < *dia-*, between + *legein*, to choose, talk: see LOGIC] 1. the sum total of local characteristics of speech 2. the sum total of an individual's characteristics of speech; idiolect 3. any form of speech considered as deviating from a real or imaginary standard speech 4. the form or variety of a spoken language peculiar to a region, community, social group, occupational group, etc.: in this sense, *dialects* are regarded as being, to some degree, mutually intelligible while *languages* are not mutually intelligible 5. any language as a member of a group or family of languages [English is a West Germanic *dialect*] —*adj.* of or in dialect [*dialect* ballads] —**di′a·lec′tal** *adj.* —**di′a·lec′tal·ly** *adv.*

SYN.—**dialect**, in this comparison, refers to a form of a language peculiar to a locality or group and differing from the standard language in matters of pronunciation, syntax, etc.; **vernacular** today commonly refers to the informal or colloquial variety of a language as distinguished from the formal or literary variety; **cant**, in this connection, refers to the distinctive stock words and phrases used by a particular sect, class, etc. [clergymen's *cant*]; **jargon** is used of the special vocabulary and idioms of a particular class, occupational group, etc., esp. by one who is unfamiliar with these; **argot** refers esp. to the secret jargon of thieves and tramps; **lingo** is a humorous or mildly contemptuous term applied to any language, dialect, or jargon by one to whom it is unintelligible

dialect atlas *same as* LINGUISTIC ATLAS

dialect geography *same as* LINGUISTIC GEOGRAPHY

di·a·lec·tic (dī′ə lek′tik) *n.* [ME. *dialetik* < OFr. *dialetique* < L. *dialectica* (*ars*) < Gr. *dialektikē* (*technē*), the dialectic (art) < *dialektikos*: see DIALECT] 1. [*often pl.*] the art or practice of examining opinions or ideas logically, often by the method of question and answer, so as to determine their validity 2. logical argumentation 3. [*often pl.*] *a)* the method of logic used by Hegel and adapted by Marx to observable social and economic processes: it is based on the principle that an idea or event (*thesis*) generates its opposite (*antithesis*) leading to a reconciliation of opposites (*synthesis*) *b)* the general application of this principle in analysis, criticism, exposition, etc. —*adj. same as* DIALECTICAL

di·a·lec·ti·cal (-ti k'l) *adj.* 1. of or using dialectic or dialectics 2. of or characteristic of a dialect; dialectal —**di′a·lec′ti·cal·ly** *adv.*

dialectical materialism the philosophy stemming from Marx and Engels which applies Hegel's dialectical method to observable social processes and to nature

di·a·lec·ti·cian (dī′ə lek tish′ən) *n.* [Fr. *dialecticien*] 1. an expert in dialectic; logician 2. a specialist in dialects

di·a·lec·tol·o·gy (-täl′ə jē) *n.* the scientific study of dialects —**di′a·lec·tol′o·gist** *n.* —**di′a·lec′to·log′i·cal** (-tə läj′i k'l) *adj.* —**di′a·lec′to·log′i·cal·ly** *adv.*

di·al·lage (dī′ə lij) *n.* [Fr. < Gr. *diallagē*, change, interchange < *diallassein*, to interchange < *dia*, through + *allassein*, to alter < *allos*, other (see ELSE): so named from having unlike fracture planes] a dark-green mineral that is a laminated variety of pyroxene

di·a·log (dī′ə lôg′, -läg′) *n.*, *v. same as* DIALOGUE

di·a·log·i·cal (dī′ə läj′i k'l) *adj.* of or marked by dialogue: also **di′a·log′ic** —**di′a·log′i·cal·ly** *adv.*

di·al·o·gist (dī al′ə jist, dī′ə lôg′ist, -läg′-) *n.* 1. a writer of dialogue 2. a person who takes part in a dialogue —**di·al·o·gis·tic** (dī′ə lô jis′tik) *adj.*

di·a·logue (dī′ə lôg′, -läg′) *n.* [ME. *dialog* < OFr. *dialogue* < L. *dialogus* < Gr. *dialogos* < *dialegesthai*: see DIALECT] 1. a talking together; conversation 2. interchange and discussion of ideas, esp. when open and frank, as in seeking mutual understanding or harmony 3. a written work in the form of a conversation 4. the passages of talk in a play, story, radio act, etc. —*vi.* **-logued′**, **-logu′ing** to hold a conversation —*vt.* to express in dialogue

Dialogue Mass *R.C.Ch.* a Low Mass at which the congregation, following an earlier custom now revived, makes the responses aloud and in unison

☆**dial tone** a low buzzing sound indicating to the user of a dial telephone that the line is open and a number may be dialed

di·al·y·sis (dī al′ə sis) *n.*, *pl.* **-ses′** (-sēz′) [L. < Gr., separation, dissolution < *dialyein*, to separate, dissolve < *dia-*, apart + *lyein*, LOOSE] the separation of crystalloids or dissolved substances from colloids in solution by the greater diffusibility of the smaller molecules through a semipermeable membrane: used as in the mechanical elimination of impurities from the blood during kidney failure —**di·a·lyt·ic** (dī′ə lit′ik) *adj.* —**di′a·lyt′i·cal·ly** *adv.*

di·a·lyze (dī′ə līz′) *vt.* **-lyzed′**, **-lyz′ing** to apply dialysis to or separate by dialysis —*vi.* to undergo dialysis

di·a·lyz·er (-lī′zər) *n.* an apparatus for dialyzing, esp. one used as an artificial kidney

diam. diameter

di·a·mag·net·ic (dī′ə mag net′ik) *adj.* having or relating to diamagnetism —*n.* a diamagnetic substance, as bismuth or zinc: also **di′a·mag′net**

di·a·mag·net·ism (-mag′nə tiz'm) *n.* 1. the property that certain substances have of being repelled by both poles of a magnet and hence taking a position at right angles to the magnet's line of influence 2. diamagnetic force 3. diamagnetic phenomena 4. the science that deals with such phenomena and substances

di·a·man·té (dē′ə män tā′, -män′tā; *Fr.* dyä mäṅ tā′) *adj.* [Fr. < pp. of *diamanter*, to tinsel, lit., set with diamonds < *diamant*, DIAMOND] decorated with rhinestones or with other brightly glittering bits of material [*diamanté* sandals] —*n.* glittering ornamentation

di·am·e·ter (dī am′ət ər) *n.* [ME. & OFr. *diametre* < ML. *diametra* < L. *diametrus* < Gr. *diametros* < *dia-*, through + *metron*, a measure: see METER¹] 1. a straight line passing through the center of a circle, sphere, etc. from one side to the other 2. the length of such a line; width or thickness of a circular, or somewhat circular, figure or object 3. *Optics* the unit of measure of the magnifying power of a lens

di·a·met·ri·cal (dī′ə met′ri k'l) *adj.* 1. of or along a diameter: also **di·am·e·tral** (dī am′ə trəl) 2. designating an opposite, a contrary, a difference, etc. that is wholly so; complete [*diametrical* opposites]: also **di′a·met′ric** —**di′a·met′ri·cal·ly** *adv.*

di·am·ine (dī am′ēn, -in; dī′ə mēn′) *n.* any of a group of chemical compounds containing two NH_2 radicals; double amine

di·a·mond (dī′mənd, -ə mənd) *n.* [ME. *diamaunt* < OFr. *diamant* < ML. *diamas* (gen. *diamantis*), for L. *adamas* < Gr. *adamas*, adamant, diamond] 1. a mineral consisting of nearly pure carbon in crystalline form, usually colorless, the hardest natural substance known: transparent, unflawed stones are cut into precious gems of great brilliance; less perfect forms are used for cutting tools, abrasives, phonograph-needle tips, etc. 2. a gem or other piece cut from this mineral 3. *a)* a lozenge-shaped plane figure (◊) *b)* a red mark like this, used for one of the four suits of playing cards *c)* [*pl.*] this suit *d)* a card of this suit ☆4. *Baseball* *a)* the infield *b)* the whole playing field —*adj.* of, like, or set with a diamond or diamonds —*vt.* to adorn with or as with diamonds —**diamond in the rough** 1. a diamond in its natural state 2. a person or thing of fine quality but lacking polish

diamond anniversary the sixtieth, or sometimes seventy-fifth, anniversary of an event

di·a·mond·back (-bak′) *adj.* having diamond-shaped markings on the back —*n.* ☆1. a large, poisonous rattlesnake (*Crotalus adamanteus*) with diamond-shaped markings on its back, native to the S U.S. ☆2. an edible turtle (*Malaclemys terrapin*) with diamond-shaped markings on its shell, found in coastal salt marshes from Cape Cod to Mexico: in full, **diamondback terrapin** 3. a small, brown and white cosmopolitan moth (*Plutella maculipennis*) whose wings, when folded, form a diamond

Diamond Head promontory in Honolulu, Hawaii

optic axis in a crystal not hav[illegible]me properties in all directions with regard to [illegible], a direction along which there is no apparent double refraction since both components of the light ray have the same velocity

optic disk *same as* BLIND SPOT (sense 1)

op·ti·cian (äp tish′ən) *n.* [Fr. *opticien*] a person who makes or deals in optical instruments, esp. one who prepares and dispenses eyeglasses

optic nerve either of the second pair of cranial nerves, which connect the retina of the eye with the brain

op·tics (äp′tiks) *n.pl.* [*with sing. v.*] [< OPTIC] the branch of physics dealing with the nature and properties of light and vision

op·ti·mal (äp′tə məl) *adj.* [OPTIM(UM) + -AL] most favorable or desirable; best; optimum —op′ti·mal·ly *adv.*

op·ti·mism (-miz′m) *n.* [Fr. *optimisme* < L. *optimus*, best (see OPTIMUM)] 1. *Philos.* *a*) the doctrine held by Leibniz and others that the existing world is the best possible *b*) the doctrine or belief that good ultimately prevails over evil 2. the tendency to take the most hopeful or cheerful view of matters or to expect the best outcome; practice of looking on the bright side of things —op′ti·mist (-mist) *n.* —op′ti·mis′tic (-mis′tik), op′ti·mis′ti·cal *adj.* —op′ti·mis′ti·cal·ly *adv.*

op·ti·mize (-mīz′) *vi.* -mized′, -miz′ing to be given to optimism —*vt.* to make the most of; develop or realize to the utmost extent; obtain the most efficient or optimum use of —op′ti·mi·za′tion *n.*

op·ti·mum (-məm) *n.*, *pl.* -mums, -ma (-mə) [L., neut. of *optimus*, best < *ops*, power, riches: for base see OPUS] 1. the best or most favorable degree, condition, amount, etc. 2. *Biol.* the amount of heat, light, moisture, food, etc. most favorable for growth and reproduction —*adj.* most favorable or desirable; best; optimal

op·tion (äp′shən) *n.* [Fr. < L. *optio* < *optare*, to wish, desire, ult. < IE. base **op-*, to choose, prefer] 1. the act of choosing: choice 2. the power, right, or liberty of choosing 3. something that is or can be chosen; choice 4. the right, acquired for a consideration, to buy, sell, or lease something at a fixed price, sign or renew a contract, etc. within a specified time —☆*vt.* *Sports* to transfer (a player) to a minor league with the option of recalling him —*SYN.* see CHOICE

op·tion·al (-'l) *adj.* left to one's option, or choice; not compulsory; elective —op′tion·al·ly *adv.*

op·to·e·lec·tron·ics (äp′tō i lek′trän′iks) *n.pl.* a branch of electronics involving the use of optical technology —op′to·e·lec′tron′ic *adj.*

op·tom·e·ter (äp täm′ə tər) *n.* [see OPTIC & -METER] an instrument for determining error in the refractive power of the eye

☆op·tom·e·trist (-trist) *n.* a specialist in optometry

op·tom·e·try (-trē) *n.* [see OPTIC & -METRY] 1. measurement of the range and power of vision 2. the profession of examining the eyes and measuring errors in refraction and of prescribing glasses to correct these defects —op·to·met·ric (äp′tə met′rik), op′to·met′ri·cal *adj.*

op·u·lent (äp′yə lənt) *adj.* [L. *opulentus* or *opulens* < *ops*: see OPUS] 1. very wealthy or rich 2. characterized by abundance or profusion; luxuriant —*SYN.* see RICH —op′u·lence, op′u·len·cy *n.* —op′u·lent·ly *adv.*

o·pun·ti·a (ō pun′shē ə, -shə) *n.* [ModL. < L. (*herba*) *Opuntia*, (plant) of Opus, city in Locris, Greece] any of a large genus (*Opuntia*) of cactus plants with red, purple, or yellow flowers, pulpy or dry berries, and fleshy, jointed stems, including the prickly pears and chollas

o·pus (ō′pəs) *n.*, *pl.* o·pe·ra (ō′pə rə, äp′ər ə), o′pus·es [L., a work < IE. **ops* < base **op-*, to work, riches, whence L. *ops*, riches, Sans. *ápas-*, work, OE. *efnan*, to work, do] a work; composition; esp., any of the musical works of a composer numbered in order of composition or publication

o·pus·cule (ō pus′kyōōl) *n.* [Fr. < L. *opusculum*, dim. of *opus*: see prec.] a minor work —o·pus′cu·lar *adj.*

-o·py (ō′pē) *same as* -OPIA

☆o·quas·sa (ō kwas′ə) *n.* [< *Oquassa* Lake, in Maine] a small trout (*Salvelinus oquassa*) of lakes of W Maine

or[1] (ôr; *unstressed* ər) *conj.* [ME., in form a contr. of *other*, *auther*, either, but actually < OE. *oththe* (in *āther* . . . *oththe*, either . . . or)] a coordinating conjunction introducing an alternative; specif., *a*) introducing the second of two possibilities [beer *or* wine] *b*) introducing any of the possibilities in a series, but usually used only before the last [apples, (*or*) pears, *or* plums] *c*) introducing a synonymous word or phrase [botany, *or* the science of plants] *d*) introducing the second of two possibilities when the first is introduced by *either* or *whether* [either go *or* stay, whether to go *or* stay] *e*) substituted for *either* as the first correlative ["*or* in the heart *or* in the head"]

or[2] (ôr) *conj.*, *prep.* [ME. < OE. *ār*, var. of *ǣr*, *ere*: cf. ERE] [Archaic or Dial.] before; ere

or[3] (ôr) *n.* [Fr. < L. *aurum*, gold: for IE. base see EAST] *Heraldry* gold or yellow, represented in engraving by small dots powdered over a plain field

-or (ər; *occas.* ôr) 1. [ME. *-our* < OFr. *-our*, *-or*, *-eur* < L. *-or*, *-ator*] *a n.-forming* [illegible] *meaning* a person or thing that [*inventor*, *objector*] [illegible]E. *-our* < OFr. < L. *-or*] *a n.-forming suffix meaning* quality or condition [*horror*, *error*]: in Brit. usage, often -our

‡o·ra (ôr′ə) *n. pl. of* OS[2]

or·ach, or·ache (ôr′əch, är′-) *n.* [ME. *orage* < Anglo-Fr. *orache* < OFr. *arroche* < VL. **atrapica* (for L. *atriplex*) < Gr. *atraphaxys*] any of a genus (*Atriplex*) of plants of the goosefoot family, widespread in salty or alkaline areas, having usually silvery foliage and small green flowers; esp., garden orach (*Atriplex hortensis*), cultivated as a potherb, chiefly in France

or·a·cle (ôr′ə k'l, är′-) *n.* [ME. < OFr. < L. *oraculum*, divine announcement, oracle < *orare*, to speak, pray, beseech < *os* (gen. *oris*), the mouth: see ORAL] 1. among the ancient Greeks and Romans, *a*) the place where, or medium by which, deities were consulted *b*) the revelation or response of a medium or priest 2. *a*) any person or agency believed to be in communication with a deity *b*) any person of great knowledge or wisdom *c*) opinion or statements of any such oracle 3. the holy of holies of the ancient Jewish Temple: I Kings 6:16, 19–23

o·rac·u·lar (ô rak′yoo lər) *adj.* 1. of, or having the nature of, an oracle 2. like an oracle; wise, prophetic, mysterious, etc. —o·rac′u·lar′i·ty (-yə lar′ə tē) *n.* —o·rac′u·lar·ly *adv.*

o·rad (ôr′ad) *adv.* [< L. *os* (gen. *oris*), the mouth + -AD[2]] toward the mouth or oral region

O·ra·dea (ô räd′yä) city in NW Romania, near the Hungarian border: pop. 112,000

o·ral (ôr′əl) *adj.* [< L. *os* (gen. *oris*), the mouth < IE. base **ōus-*, mouth, edge, whence Sans. *ā-h*, mouth, ON. *óss*, mouth of a stream] 1. uttered by the mouth; spoken 2. of speech; using speech 3. of, at, or near the mouth 4. *Phonet.* having mouth resonance only: distinguished from NASAL 5. *Psychoanalysis* *a*) designating or of the earliest stage of psychosexual development in which interest centers around sucking, feeding, and biting *b*) designating or of such traits in the adult as friendliness, generosity, and optimism or aggressiveness and pessimism, regarded as unconscious psychic residues of that stage: cf. ANAL, GENITAL 6. *Zool.* on or of the same side as the mouth —☆*n.* an examination that is oral and not written, as in a college —o′ral·ly *adv.*

SYN.—**oral** refers to that which is spoken, as distinguished from that which is written or otherwise communicated [*an oral promise, request, etc.*]; verbal, though sometimes synonymous with oral, in strict discrimination refers to anything using words, either written or oral, to communicate an idea or feeling [*a verbal image, caricature, etc.*]

oral history 1. historical data consisting of personal recollections, usually in the form of a tape-recorded interview 2. the gathering and preservation of such data

o·ral·ism (ôr′əl iz′m) *n.* the theory or practice of teaching the deaf to read lips and to speak —o′ral·ist *adj.*, *n.*

O·ran (ō ran′; *Fr.* ô rän′) seaport in N Algeria, on the Mediterranean: pop. 430,000

o·rang (ō raŋ′, ə-) *n. same as* ORANGUTAN

Or·ange[1] (ôr′inj, är′-) ruling family of the Netherlands: see NASSAU —*adj.* of or having to do with Orangemen

Or·ange[2] (ôr′inj, är′-; *also, for 3 & 4, Fr.* ô ränzh′) 1. [prob. after the *orange* groves there] city in SW Calif.: suburb of Los Angeles: pop. 92,000 2. river in South Africa, flowing from NE Lesotho west into the Atlantic: c. 1,300 mi. 3. former principality of W Europe, now in SE France 4. city in SE France: pop. 21,000

or·ange (ôr′inj, är′-) *n.* [ME. < OFr. *orenge* < Pr. *auranja* (with sp. influenced by L. *aurum*, gold & loss of initial *n* through faulty separation of art. *un*) < Sp. *naranja* < Ar. *nāranj* < Per. *nārang* < Sans. *naranga*, prob. akin to Tamil *naṛu*, fragrant] 1. a reddish-yellow, round, edible citrus fruit, with a sweet, juicy pulp 2. any of various evergreen trees (genus *Citrus*) of the rue family producing this fruit, having white, fragrant blossoms, often carried by brides, and hard, yellow wood 3. any of several plants or fruits resembling the orange 4. reddish yellow —*adj.* 1. reddish-yellow 2. made with or from orange 3. having a flavor like that of oranges —or′ang·y (-in jē) *adj.*

or·ange·ade (-ād′) *n.* [Fr.: see ORANGE & -ADE] a drink made of orange juice and water, usually sweetened

Orange Free State province of South Africa, west of Lesotho: formerly a Boer republic (1854–1900) & then a Brit. colony (Orange River Colony, 1900–10): 49,866 sq. mi.; pop. 1,387,000; cap. Bloemfontein

☆orange hawkweed *same as* DEVIL'S PAINTBRUSH

Or·ange·ism (ôr′inj iz′m, är′-) *n.* the principles and practices of the Orangemen

Or·ange·man (-mən) *n.*, *pl.* -men (-mən) [after the Prince of *Orange*, later WILLIAM III] a member of a secret Protestant society organized in N Ireland (1795)

orange pekoe a black tea of Ceylon and India: see PEKOE

or·ange·ry (ôr′inj rē, är′-) *n.*, *pl.* -ries [Fr. *orangerie* < *oranger*, orange tree < *orange*] a hothouse or other sheltered place for growing orange trees in cooler climates

☆orange stick a pointed stick, orig. of orangewood, used in manicuring

☆**no-show** (nō′shō′) *n.* [Colloq.] a person who makes a reservation, as for an airline flight, but fails to claim or cancel it
nos·ing (nō′ziŋ) *n.* [NOSE + -ING] 1. the projecting edge of a step; that part of the tread which extends beyond the riser 2. a strip, as of metal, for protecting this edge from wear 3. any projection like a stair nosing
nos·o- (näs′ō) [< Gr. *nosos*, disease] *a combining form meaning* disease *[nosology]:* also, before a vowel, **nos-**
no·sog·ra·phy (nō säg′rə fē) *n.* [prec. + -GRAPHY] the systematic description of diseases
no·sol·o·gy (nō säl′ə jē) *n.* [ModL. *nosologia:* see NOSO- & -LOGY] 1. classification of diseases 2. the branch of medicine dealing with this —**nos·o·log·ic** (näs′ə läj′ik), **nos′o·log′i·cal** *adj.* —**nos′o·log′i·cal·ly** *adv.*
nos·tal·gia (näs tal′jə, nəs-, nôs-; -jē ə) *n.* [ModL. < Gr. *nostos*, a return + -ALGIA] 1. a longing to go back to one's home, home town, or homeland; homesickness 2. a longing for something far away or long ago or for former happy circumstances —**nos·tal′gic** (-jik) *adj.* —**nos·tal′gi·cal·ly** *adv.*
nos·toc (näs′täk) *n.* [ModL., coined by Paracelsus] any of a genus (*Nostoc*) of blue-green algae, having twisted, coiled filaments embedded in a gelatinous material and forming spherical colonies
nos·tol·o·gy (näs täl′ə jē) *n.* [< Gr. *nostos*, a return + -LOGY] *earlier term for* GERONTOLOGY —**nos′to·log′ic** (-tə läj′ik) *adj.*
nos·to·ma·ni·a (näs′tə mā′nē ə, -mān′yə) *n.* [ModL. < Gr. *nostos*, a return + -MANIA] *Psychiatry* excessive or abnormal nostalgia
Nos·tra·da·mus (näs′trə dā′məs, nō′strə dā′məs) (born *Michel de Notredame*) 1503–66; Fr. astrologer
nos·tril (näs′trəl) *n.* [ME. *nosethirl* < OE. *nosthyrl* < *nos*, for *nosu*, the nose + *thyrel*, a hole < *thurh*, through: see NOSE & THROUGH] 1. either of the external openings of the nose 2. the fleshy wall on either side of the nose *[with flaring nostrils]*
nos·trum (näs′trəm) *n.* [L., neut. of *noster*, ours: ? so called from the seller's calling it "our" remedy] 1. *a)* a medicine prepared by the person selling it *b)* a patent medicine of a kind sold with exaggerated claims; quack medicine 2. a pet scheme for solving some social or political problem; panacea
nos·y (nō′zē) *adj.* **nos′i·er, nos′i·est** [NOS(E) + -Y²] [Colloq.] given to prying; inquisitive —**nos′i·ly** *adv.* —**nos′i·ness** *n.*
Nosy Parker (pär′kər) [NOSY + proper name *Parker:* reason for use uncertain] [*also* **n- p-, n- P-**] [Colloq.] a nosy person; busybody
not (nät) *adv.* [ME. *not*, unstressed form of *noht, nought, naught:* see NOUGHT] in no manner; to no degree: a particle of negation, or word expressing the idea of *no*, often implying refusal, affirmation of the opposite, etc.: sometimes used elliptically *[whether you like it or not]*
not- (nōt) *same as* NOTO-: used before a vowel
‡**no·ta be·ne** (nō′tə bē′nē, nō′tä be′nā) [L.] note well; take particular notice
no·ta·bil·i·a (-bil′ē ə, -bil′yə) *n.pl.* [L., neut. pl. of *notabilis:* see ff.] things worthy of notice
no·ta·bil·i·ty (nōt′ə bil′ə tē) *n.* 1. *pl.* **-ties** a person who is notable or prominent 2. the quality of being notable
no·ta·ble (nōt′ə b′l; *for adj. 2, also* nät′-) *adj.* [ME. < OFr. < L. *notabilis* < *notare*, to mark, note < *nota*, a mark: see NOTE] 1. worthy of notice; remarkable; outstanding 2. [Archaic] industrious and capable, as in housekeeping —*n.* 1. a person of distinction; famous or well-known person 2. [N-] formerly in France, any of the persons of authority, rank, etc. summoned by the king as a deliberative assembly in emergencies —**no′ta·bly** *adv.*
no·tar·i·al (nō ter′ē əl) *adj.* 1. of or characteristic of a notary public 2. drawn up or executed by a notary public —**no·tar′i·al·ly** *adv.*
☆**no·ta·rize** (nōt′ə rīz′) *vt.* **-rized′, -riz′ing** to certify or attest (a document) as a notary public, esp. with a signature seal —**no′ta·ri·za′tion** *n.*
no·ta·ry (nōt′ər ē) *n., pl.* **-ries** [ME. *notarye* < OFr. *notaire* < L. *notarius* < *notare*, to NOTE] *clipped form of* NOTARY PUBLIC
notary public *pl.* **notaries public, notary publics** an official authorized to certify or attest documents, take depositions and affidavits, etc.
no·ta·tion (nō tā′shən) *n.* [L. *notatio* < *notare*, to NOTE] 1. the use of a system of signs or symbols to represent words, phrases, numbers, quantities, etc. 2. any such system of signs or symbols, as in mathematics, chemistry, music, etc. 3. a brief note jotted down, as to remind one of something, explain something, etc. 4. the act of noting something in writing —**no·ta′tion·al** *adj.*
notch (näch) *n.* [prob. by syllabic merging of ME. *an oche* < OFr. *oche, osche*, a notch < *oschier*, to notch] 1. a concave or V-shaped cut or indentation in an edge or across a surface ☆2. a narrow pass with steep sides; defile; gap 3. [Colloq.] a step; grade; degree; peg *[a notch below average]* —*vt.* 1. to cut a notch or notches in; indent with notches 2. to record or tally, as by means of notches —**notched** *adj.* —**notch′er** *n.*

note (nōt) *n.* [ME. < OFr. < L. *nota*, a mark, sign, character, letter < *notus*, pp. of *noscere*, to know < *gnoscere:* for IE. base see KNOW] 1. a mark of some quality, condition, or fact; distinguishing or characteristic feature, mood, tone, etc. *[a note of sadness]* 2. importance, distinction, or eminence *[a person of note]* 3. *a)* a brief statement of a fact, experience, etc. written down for review, as an aid to memory, or to inform someone else; memorandum *b)* [*pl.*] a record of experiences, etc. *[the notes of a journey]* 4. a comment, explanation, or elucidation, as at the foot of a page; annotation 5. notice; heed; observation *[worthy of note]* 6. any of certain types of correspondence; specif., *a)* a short, informal letter *b)* a formal diplomatic or other official communication 7. *a)* any of certain commercial papers, some of which are negotiable, relating to the owing of debts or payment of money *[a promissory note]* *b)* a piece of paper currency *[a Federal Reserve note]* 8. a cry or call, as of a bird 9. a signal or intimation *[a note of admonition]* 10. [Archaic or Poet.] a melody, tune, or song 11. *Music a)* a tone of definite pitch, as made by a voice or musical instrument *b)* a symbol for a tone, indicating the duration by its form and the pitch by its position on the staff *c)* a key of a piano or the like —*vt.* **not′ed, not′ing** [ME. *noten* < OFr. *noter* < L. *notare* < *nota*] 1. to pay close attention to; heed; notice; observe 2. to set down in writing; make a note of 3. to mention particularly 4. to denote, signify, or indicate 5. to set down in musical notes —**compare notes** to exchange views; discuss —**strike the right note** to say, write, or do what is specially apt or pleasing —**take notes** to write down notes, as during a lecture or interview, for later reference

NOTES
(A, whole; B, half; C, quarter; D, eighth; E, sixteenth; F, thirty-second; G, sixty-fourth)

note·book (nōt′book′) *n.* a book in which notes, or memorandums, are kept
note·case (-kās′) *n.* [Brit.] *same as* BILLFOLD
not·ed (nōt′id) *adj.* distinguished; well-known; renowned; eminent —*SYN.* see FAMOUS —**not′ed·ly** *adv.* —**not′ed·ness** *n.*
note·less (nōt′lis) *adj.* 1. not noted; unnoticed; undistinguished 2. unmusical
note of hand *same as* PROMISSORY NOTE
note paper paper for writing notes, or letters
note·wor·thy (-wur′thē) *adj.* worthy of note; deserving notice; outstanding; remarkable; notable —**note′wor′thi·ly** *adv.* —**note′wor′thi·ness** *n.*
noth·ing (nuth′iŋ) *n.* [ME. < OE. *na thing, nan thing*] 1. *a)* no thing; not anything; nought *b)* no part, element, trace, etc. *[nothing of kindness in him]* 2. *a)* nonexistence; nothingness *b)* insignificance; unimportance 3. a thing that does not exist 4. *a)* something of little or no value, seriousness, importance, etc.; triviality or trifle *b)* a person considered of no value or importance 5. a nought; zero; cipher —*adv.* not at all; in no manner or degree *[nothing daunted]* —**for nothing** 1. free; at no cost 2. in vain; uselessly 3. without reason —☆**have nothing on** to have no implicating evidence, information, etc. about —☆**in nothing flat** [Colloq.] in almost no time at all —**make nothing of** 1. to treat as of little importance 2. to fail to understand —**nothing but** only; nothing other than —**nothing doing** [Colloq.] 1. no: used as a refusal of a request 2. no result, accomplishment, etc.: an exclamation of disappointment —**nothing less than** no less than; just the same as: also **nothing short of** —**think nothing of** 1. to attach no importance to 2. to regard as easy to do
noth·ing·ness (-nis) *n.* 1. the quality or condition of being nothing or not existing; nonexistence or extinction 2. lack of value, worth, meaning, etc.; uselessness, emptiness, insignificance, etc. 3. unconsciousness or death 4. anything that is nonexistent, worthless, insignificant, useless, etc.
no·tice (nōt′is) *n.* [LME. < MFr. < L. *notitia* < *notus:* see NOTE] 1. information, announcement, or warning; esp., formal announcement or warning, as in a newspaper *[a legal notice]* 2. a brief mention or critical review of a work of art, book, play, etc. 3. a written or printed sign giving some public information, warning, or rule 4. *a)* the act of observing; attention; regard; heed; cognizance *b)* courteous attention; civility 5. a formal announcement or warning of intention to end an agreement, relation, or contract at a certain time *[to give a tenant notice]* —*vt.* **-ticed, -tic·ing** 1. *a)* to mention; refer to; comment on *b)* to review briefly 2. *a)* to regard; observe; pay attention to *b)* to be courteous or responsive to 3. [Rare] to serve with a formal notice —*SYN.* see DISCERN —**serve notice** to give formal warning or information, as of intentions; announce —**take notice** to become aware; pay attention; observe

Office Action Summary	Application No.	Applicant(s)	
	09/905,683	GROOMS ET AL.	
	Examiner	Art Unit	
	Bruce E. Snow	3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 December 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *111-118 and 120-136* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *111-118, 120-136* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Response to Arguments

Applicant's arguments filed April 18, 2005, have been fully considered.

The provisionally provisional double patenting rejection under 35 U.S.C. 101 as claiming the same invention as that of all claims of copending Application No. 10/375,540 has been withdrawn; 10/375,540 has been abandoned.

Regarding the rejection under 35 U.S.C. 102(b) as being anticipated by Albee (Bone Surgery with Machine Tools), applicant has amended claim 1 to include a "circular" through hole which is shown in at least figure 3, sub-figure 10 of Albee. Applicant has also amended claim 1 to include the limitation "*said assembled bone implant being suitable for implantation into said patient*". It is the Examiner's position that the assembled bone portions of Albee are capable of being used as a donor tissue and implanted into a second patient which fulfills all functional language. MPEP 2114 teaches:

> **APPARATUS CLAIMS MUST BE STRUCTUR-ALLY DISTINGUISHABLE FROM THE PRIOR ART**
>
> >While features of an apparatus may be recited either structurally or functionally, claims directed to an apparatus must be distinguished from the prior art in terms of structure rather than function. >*In re Schreiber*, 128 F.3d 1473, 1477-78, 44 USPQ2d 1429, 1431-32 (Fed. Cir. 1997
>
> **MANNER OF OPERATING THE DEVICE DOES NOT DIFFERENTIATE APPARATUS CLAIM FROM THE PRIOR ART**
>
> A claim containing a "recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus" if the prior art apparatus teaches all the structural limitations of the claim. *Ex parte Masham*, 2 USPQ2d 1647 (Bd. Pat. App. & Inter. 1987)

As previously stated by the Examiner, additionally, in situations of multiple breaks, it is conceivable that bone portions are connected together outside of the body and than placed back, such as skull fractures.

Regarding the D-shape limitation, it is the Examiner's position that D-shape is not limited to including a D-shape hole. The Examiner knows of that D-shape is used to describe the head of a nail (for a nail gun) which does not have a hole. The Examiner suggests adding the limitation to the claims.

Note figure 3, sub-figures 1, 2a 10, 11, 12, 15 which are interpreted as having through holes. Note the holes of sub-figures 11-12 extend through the front to back. The Examiner notes applicant's arguments regarding some of the figures are joinery techniques. However, Albee is teaching these can be used with bone. Referring to at least figure 3, sub-figure 15, it is unclear why applicant does not believe this is bone, however, it is clear to one having ordinary skill in the art interpreting the teachings of Albee, that this could be bone.

Claim 126, requires at the first and second portions being superimposed to form a D-shape, which is not taught or shown in figure 3, sub-figures 11-12.

Regarding the rejection under 35 U.S.C. 103(a) as being unpatentable over Coates et al (5,989,289) in view of Siebels (EP 517030), applicant's argument is not fully understood nor persuasive. Coates et al, despite the difficulty of manufacturing, teaches a D-shaped cortical bone implant:

(31) The spacers of this invention are preferably formed of a bone composition or material. The bone may be autograft, allograft, xenograft or

any of the above prepared in a variety of ways. Cortical bone is preferred for its compressive strength. In one embodiment, the spacers are obtained as a cross sectional slice of a shaft of a long bone. For example, various shaped spacers may be obtained by machining a cortical ring into the desired configuration. The exterior surfaces of the walls can be formed by machining the ring to a D-shape.

It is the Examiner's position that it would have been obvious to one having ordinary skill in the art to have used the teaching of Siebels and have stacked the device of Coates to **adjustably** build the implant to a desired height (thickness) to best fill the disc space as desired by the surgeon. This combination has nothing to do with how easy or difficult it is to build either implant of Siebels and Coates; and applicant's arguments are spurious. It is noted that in page 16, second paragraph, applicant addresses the combination of Coates and Brantigan under Section III Coates over Siebel; in response to this Office action, please keep arguments to separate rejections separate.

As pervious stated:

Regarding the rejection under 35 U.S.C. 103(a) as being unpatentable over Coates et al (5,989,289) in view of Siebels (EP 517030), applicant argues that Siebels teaches connecting (stacking) implant portions because it is easier to manufacture. In response to applicant's argument, the fact that Siebels recognized another advantage of their invention does not take away from the teaching and advantage of multiple portions stacked and connected by at least one pin in corresponding through holes to adjustably build the implant to a desired height (thickness) to best fill the disc space as desired by the surgeon.

Regarding the rejection under 35 U.S.C. 103(a) as being unpatentable over Brantigan (5,192,327) in view of Coates et al (5,989,289), applicant's arguments are not persuasive.

Regarding the amendment to claim 111 including "circular through hole", circular is defined as "of or relating to a circle". Elements 14 and 24 are interpreted as being circular. Additionally, the entire opening can be interpreted as the through hole.

The Examiner notes that Brantigan does not teach cortical bone, the typo has been resolved.

Regarding the applicant's section 1., applicant argues that Brantigan teaches away from the use of metals. However, the abstract states:

> The annular implants have ample spaces to allow ingrowth of blood capillaries and packing of bone graft and are preferably made of a radiolucent material, preferably biocompatible carbon fiber reinforced polymers **or are alternately made of traditional orthopaedic implant materials such as nickel, chromium, cobalt, stainless steel or titanium.**

Again, Coates **specifically** states that the implant of Brantigan is flawed because the materials used (**including** metals) of Brantigan are too stiff which causes stress shielding, etc., as stated in the grounds of rejection. Coates in the very next paragraph teaches bone as an implant material "avoid[s] the disadvantages of metal implants"; see column 2, lines 49 et seq. It is also noted that polymeric material taught by Brantigan is foreign to the body and that *foreign bodies [which] can never be fully incorporated into the fusion mass.*

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 111-118, 120-123, 129-136 are rejected under 35 U.S.C. 102(b) as being anticipated by Albee (Bone Surgery with Machine Tools).

Referring to all figures, specifically figure 3, sub-figures 10-12 and 15, Albee teaches:

a first cortical bone portion;

a second cortical bone portion;

said first cortical bone portion and said second cortical bone portion having one or more (circular shown in at least figure 3, sub-figure 10) through holes sized and positioned for receiving one or more retention pins for
connecting said first cortical bone portion to said second cortical bone portion; and

one or more retention pins of appropriate diameter for connecting said first cortical bone portion to said second cortical bone portion to form said assembled bone implant unitary body outside the patient and suitable for implantation into said patient.

Note figure 3, subfigures 1, 2a 10, 11, 12, 15 which are interpreted as having through holes.

Albee teaches the pines are grafts which inherently comprise cortical and cancellous bone.

Regarding claim 116, mirror image, see at least sub-figure 15.

Regarding claim 121, the embodiments shown in sub-figures 11-12 are sized and shaped for in the form of a cervical implant.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 111-118 and 120-136 are rejected under 35 U.S.C. 103(a) as being unpatentable over Coates et al (5,989,289) in view of Siebels (EP 517030).

Referring to all figures, Coates teaches a D-shaped cortical bone spinal implant (see column 11, lines 42 et seq.). However, Coates et al fails to teach said implant can comprise a first and second portion capable of being connected by a pin. Siebels also teaches a spinal implant and teaches stacking portions 11 of the implant and connecting said portions with pins 17. It would have been obvious to one having ordinary skill in the art to have utilized the teachings of Siebels to stack and connect individual implant portions with the D-shaped cortical bone implant of Coates wherein multiple portions could be stacked and connected by at least one pin in corresponding through holes to adjustably build the implant to a desired height (thickness) to best fill the disc space as desired by the surgeon.

Regarding at least claims 114-115, 123, and 127, lacking any criticality in the specification, the use of the claimed materials such as titanium in lieu of those taught by Seibels produce no advantage and is considered an obvious matter of design choice. Additionally, Coates teaches the use of metal devices are foreign bodies which can never be fully incorporated in the fusion mass and produce stress shielding because the stiffness values do not match that of bone (column 2, lines 34 et seq.). Therefore, it would have been obvious to one having ordinary skill in the art to have constructed the pin out of cortical bone or cancellous bone which can be fully incorporated and does not produce stress shielding.

Regarding claim 122, see column 11, lines 62 et seq.

Regarding claims 124 and 128, Coates et al teaches treating the spacer with BMP which would include the pins.

All other claimed limitations are self-evident.

Claims 111-118 and 120-136 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brantigan (5,192,327) in view of Coates et al (5,989,289).

Referring to all figures, specifically figures 2 and 5, Brantigan teaches a D-shaped bone implant comprising:

a first portion 21;

a second portion 21;

said first portion and said second portion having one or more through holes 24 sized and positioned for receiving one or more retention pins 15 for connecting said first cortical bone portion to said second cortical bone portion; and

one or more retention pins of appropriate diameter for connecting said first portion to said second portion to form said assembled bone implant unitary body.

However, Brantigan fails to teach the first and second portions are cortical bone. Brantigan teaches the device can be made of traditional orthopaedic implant materials; see the abstract. Coates et al teaches a D shaped implant can be made of cortical bone. It would have been obvious to one having ordinary skill in the art to have utilized cortical bone which is a traditional orthopaedic implant material as taught by Coates for any of the elements of Brantigan because "*5,192,327 to Brantigan teach hollow metal cage structures. Unfortunately, due to the stiffness of the material, some metal implants may stress shield the bone graft, increasing the time required for fusion or causing the bone graft to resorb inside the cage. Subsidence, or sinking of the device into bone, may also occur when metal implants are implanted between vertebrae if fusion is delayed. Metal devices are also foreign bodies which can never be fully incorporated into the fusion mass.*" See column 2, lines 40 et seq. of Coates. Additionally, "cortical bone with the advantage of incorporation of the spacer material without stress shielding."

Regarding the amendment to claim 111 including "circular through hole", circular is defined as "of or relating to a <u>circle</u>". Elements 14 and 24 are interpreted as being circular. Additionally, the entire opening can be interpreted as the through hole.

Regarding at least claims 114-115, 123, and 127, the combination at least teaches titanium or cortical bone, lacking any criticality in the specification, the use of the specific use of any claimed materials for the pin in lieu of those taught by references produces no advantage and is considered an obvious matter of design choice. Additionally, Coates teaches the use of metal devices are foreign bodies which can never be fully incorporated in the fusion mass and produce stress shielding because the stiffness values do not match that of bone (column 2, lines 34 et seq.). Therefore, it would have been obvious to one having ordinary skill in the art to have constructed the pin out of cortical bone or cancellous bone which can be fully incorporated and does not produce stress shielding.

Regarding claims 124 and 128, Coates et al teaches treating the spacer with BMP which would include the pins.

All other claimed limitations are self-evident.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bruce E. Snow whose telephone number is (571) 272-4759. The examiner can normally be reached on Mon-Thurs.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on (571) 272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

bes

BRUCE SNOW
PRIMARY EXAMINER

Search Notes

Application No.	Applicant(s)
09/905,683	GROOMS ET AL.
Examiner	**Art Unit**
Bruce E Snow	3738

SEARCHED

Class	Subclass	Date	Examiner
623	17.11		
	17.15		
	17.16		
606	61	3/15/2004	
~~updated~~	~~Snow~~	~~12/1/04~~	~~BS~~
updated		6/13/05	BS
updated		3/6/06	BS

INTERFERENCE SEARCHED

Class	Subclass	Date	Examiner
623	17.11		
	17.16	12/1/04	BS

SEARCH NOTES (INCLUDING SEARCH STRATEGY)

	DATE	EXMR

PTO/SB/06 (08-03)
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PATENT APPLICATION FEE DETERMINATION RECORD

Substitute for Form PTO-875

Application or Docket Number: 09/905683

CLAIMS AS FILED – PART I

FOR	NUMBER FILED (Column 1)	NUMBER EXTRA (Column 2)	SMALL ENTITY RATE	SMALL ENTITY FEE	OR	OTHER THAN SMALL ENTITY RATE	OTHER THAN SMALL ENTITY FEE
BASIC FEE (37 CFR 1.16(a))				$150	OR		$300
TOTAL CLAIMS (37 CFR 1.16(c))	minus 20 =	*	x $25 =		OR	x $50 =	
INDEPENDENT CLAIMS (37 CFR 1.16(b))	minus 3 =	*	x $100 =		OR	x $200 =	
MULTIPLE DEPENDENT CLAIM PRESENT (37 CFR 1.16(d))			+ $180 =		OR	+ $360 =	
			TOTAL		OR	TOTAL	

* If the difference in column 1 is less than zero, enter "0" in column 2.

CLAIMS AS AMENDED – PART II

AMENDMENT A

12-2-05	CLAIMS REMAINING AFTER AMENDMENT (Column 1)		HIGHEST NUMBER PREVIOUSLY PAID FOR (Column 2)	PRESENT EXTRA (Column 3)	SMALL ENTITY RATE	ADDITIONAL FEE	OR	OTHER THAN SMALL ENTITY RATE	ADDITIONAL FEE
Total (37 CFR 1.16(c))	* 24	Minus	** 58	=	x $25 =		OR	x $50 =	
Independent (37 CFR 1.16(b))	* 3	Minus	*** 12	=	x $100 =		OR	x $200 =	
FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(d))					+ $180 =		OR	+ $360 =	
					TOTAL ADD'L FEE		OR	TOTAL ADD'L FEE	

AMENDMENT B

	CLAIMS REMAINING AFTER AMENDMENT (Column 1)		HIGHEST NUMBER PREVIOUSLY PAID FOR (Column 2)	PRESENT EXTRA (Column 3)	SMALL ENTITY RATE	ADDITIONAL FEE	OR	OTHER THAN SMALL ENTITY RATE	ADDITIONAL FEE
Total (37 CFR 1.16(c))	*	Minus	**	=	x $25 =		OR	x $50 =	
Independent (37 CFR 1.16(b))	*	Minus	***	=	x $100 =		OR	x $200 =	
FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(d))					+ $180 =		OR	+ $360 =	
					TOTAL ADD'L FEE		OR	TOTAL ADD'L FEE	

AMENDMENT C

	CLAIMS REMAINING AFTER AMENDMENT (Column 1)		HIGHEST NUMBER PREVIOUSLY PAID FOR (Column 2)	PRESENT EXTRA (Column 3)	SMALL ENTITY RATE	ADDITIONAL FEE	OR	OTHER THAN SMALL ENTITY RATE	ADDITIONAL FEE
Total (37 CFR 1.16(c))	*	Minus	**	=	x $25 =		OR	x $50 =	
Independent (37 CFR 1.16(b))	*	Minus	***	=	x $100 =		OR	x $200 =	
FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(d))					+ $180 =		OR	+ $360 =	
					TOTAL ADD'L FEE		OR	TOTAL ADD'L FEE	

* If the entry in column 1 is less than the entry in column 2, write "0" in column 3.
** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 20, enter "20".
*** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 3, enter "3".
The "Highest Number Previously Paid For" (Total or Independent) is the highest number found in the appropriate box in column 1.

ATTORNEY DOCKET NO. TB 104IA CA/ 1915/13971US04

IN THE UNITED STATES
PATENT AND TRADEMARK OFFICE

Applicants: **Grooms, James, *et al.***	)	**CERTIFICATE OF ELECTRONIC FILING**
U.S. Serial No.: 09/905,683	)	I hereby certify that this correspondence is being sent via electronic filing to the United States Patent and Trademark Office on this date:
Filed: July 13, 2001	)	September 11, 2006
For: "MULTI-COMPONENT CORTICAL BONE ASSEMBLED IMPLANT" **(AS AMENDED)**	)	Donald J. Pochopien Registration No. 32,167 Attorney for Applicants
Group Art Unit: 3738	)	
Examiner: Bruce Edward Snow	)	

NOTICE OF APPEAL UNDER 37 C.F.R. § 1.191

Mail Stop AF
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

In response to the final Official Action of 03/15/06, for which a Response was due 06/15/06, now extended three (3) months to 09/15/06, the Applicants hereby provide notice under 37 C.F.R. § 1.191 of their intent to appeal the rejection of all pending claims.

Respectfully submitted,

McANDREWS, HELD & MALLOY, LTD.

By: ______________________

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Suite 3400
Chicago, Illinois 60661
(312) 775-8133

Dated: September 11, 2006
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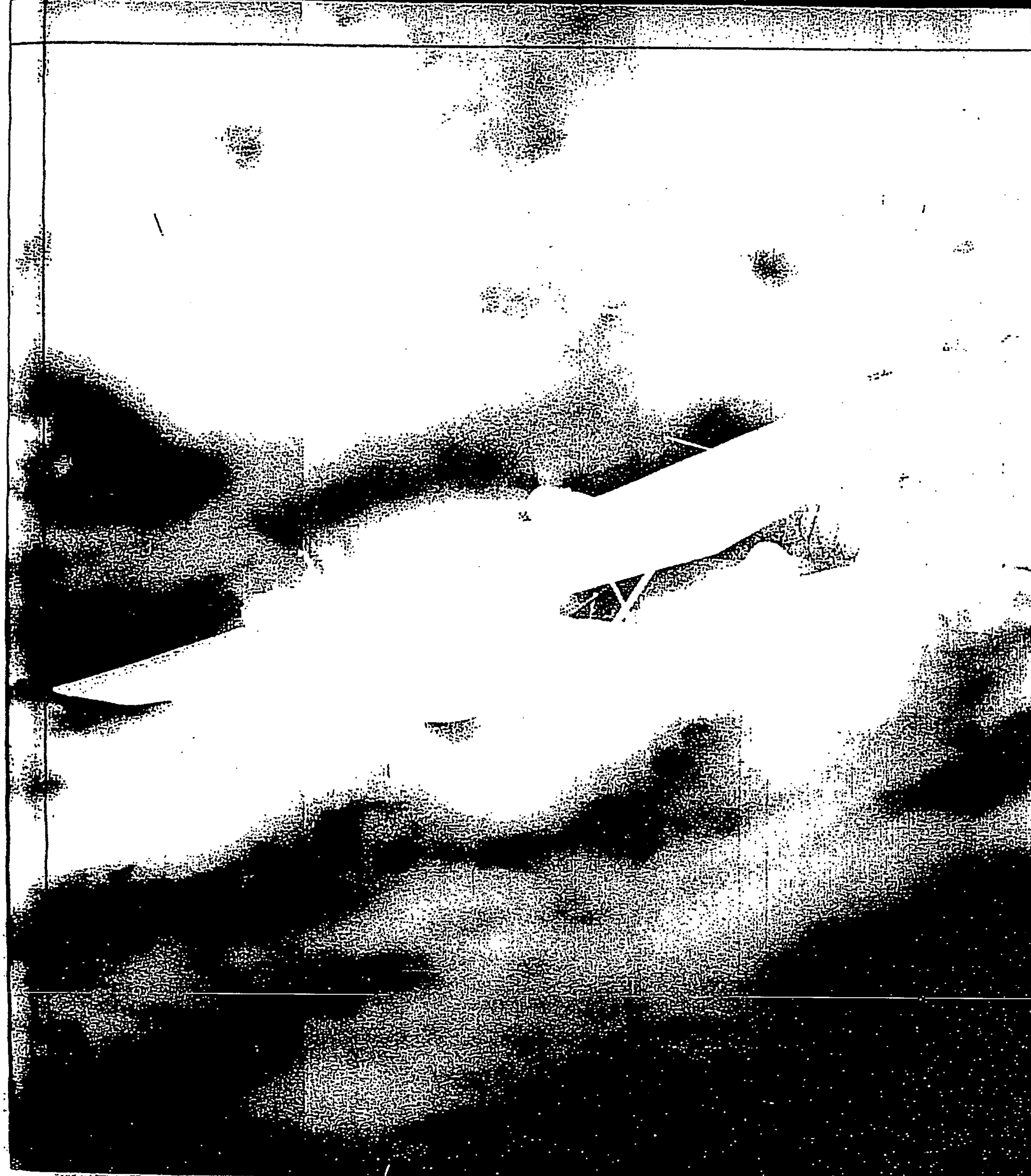

SCIENTIFIC AMERICAN

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NINETY-SECOND YEAR • ORSON D. MUNN, Editor

CONTENTS · APRIL · 1936

COVER

SYMBOLICAL of the progress that has been made in air transport operations during the past few years is the striking photograph by Richard B. Hoit, reproduced on our cover this month. Ships of the China Clipper type have been making history over the Pacific, and as pointed out by Mr. Cleveland in his article starting on page 173 of this issue, we may look forward to the probability that aviation history will repeat itself in the Atlantic sector during the present year.

The SCIENTIFIC AMERICAN DIGEST

SCIENTIFIC AMERICAN, April, 1936. Vol. No. 154, No. 4, entered at the New York, N. Y. Post Office as second class matter June 28, 1879, under the act of March 3rd, 1879; additional entry at Greenwich, Conn. Published monthly by Munn & Company, Inc., 24 West 40th Street, New York City. Copyrighted 1936 by Munn & Company, Inc. Great Britain rights reserved. Subscription price $4.00 per year. Canada $4.50. Foreign $5.00. Manuscripts are submitted at the author's risk and cannot be returned unless accompanied by postage.

BONE SURGERY WITH

Grafting Bones is Much Like Grafting Trees . . . Bone from Your Own Body . . . Cut with a Circular Saw . . . Shaped on the Spot with a Bone Mill

By FRED H. ALBEE, M.D., F.A.C.S.

Formerly Professor of Orthopedic Surgery at Columbia University. Consulting Surgeon to the Broad Street, Lutheran Hospital and other hospitals, New York. Founder of the Florida Medical Center, Venice, Florida

BY good fortune we are able to present, on the accompanying pages, an article by a noted, internationally-known bone surgeon, thus giving the lay reader a first-hand insight into a branch of surgery of the most modern and most romantic variety—the repair of damaged bones by means of living bone substance taken from the patient's own body. The author of the article became widely known at the time of the World War, first through six months of operation and demonstration in France, and later in America where he performed reconstructive operations on more than 2000 wounded American soldiers. Dr. Albee is an ex-president of the American Orthopedic Association, and a founder of the International Society of Orthopedic Surgery. He is the author of a large textbook which is widely used by surgeons, entitled "Orthopedic and Reconstruction Surgery," and he has been widely honored within his profession and without.

Bone surgery with metal plates or wire, or with pieces of hard and non-living bone, has long been familiar, but Nature often rejects such foreign substances. To repair living bone, living bone is an ideal material. Many of us think of bone as hard, dry, brittle and somewhat metallic, because most of us see it in that form. But our bones are really alive; they contain pulsating blood vessels and other living equipment. Such bone, rapidly removed from one place (often the convenient shin) and transplanted to another after accurate shaping, unites and grows to

THE origin of grafting of living cells, if recorded at all, is so obscure that I have not been able to trace it. I was not unfamiliar with the process in fruit-trees before I undertook to apply the principles to the surgery of bones. As might be expected, I found much in the study of plant grafting to guide me in bone-grafting. One can safely assume that the principles of plant grafting cannot be violated in the grafting of tissues of a higher form, and that grafting of bone cannot be as readily carried out as grafting of vegetable material.

These postulates arise from the very nature of biological principles and the decrease in adaptability with increase in specialization of tissue. There are three inviolable rules in plant-grafting: the tissues must be applied like to like, the contact must be most intimate, and they must be immobilized in that position. These principles are important in bone-grafting. Moreover, in the more highly specialized animal tissue it is desirable, if not essential, that the graft be autogenous; that is, come from the same individual.

When, in plant grafting, the bark and bud are removed for the scion, a piece of bark of the same size and shape is removed from the host (Figure 1), so that like tissues of the scion will be applied intimately to like tissues of the host and so that immobilization will be facilitated, as well as the early and profuse vegetable circulation from host to graft. Interruption of the circulation of sap in the host is thus minimized.

It is thus evident that the cells of the scion preserve their vegetative and proliferative power. The re-establishment of the circulation is simpler in the plant, but it is obvious that the sap must permeate the cells of the scion, or else the latter will eventually die. In bone, the re-establishment of circulation becomes a problem the solution of which governs the whole question of surgical technique.

IN the plant, as in bone, like tissues are applied to like, because there is a force called by John Hunter the "stimulus of incompleteness," which tends to force tissues to complete a broken surface, and because this force is greater when it is mutual—that is to say, when it is applied to two broken surfaces of like tissue.

Of all the layers in a tree—alburnum, heart-wood, and heart—the alburnum is the important one in grafting, since it is the proliferation of its cells in scion and host that brings about the union. In bone, and especially in long bones, the structure is much harder and more complex, and all the layers — periosteum, cortex, endosteum and marrow — take part, to a greater or less extent, in union. It is for this reason, and the extreme hardness and brittleness of cortical bone (the hard portion), that accurate, power-driven instruments are necessary for preparing graft and graft-bed. Perfect coaptation, so essential to the nourishment of the graft and to its function as a vessel-conducting and osteogenetic or bone-forming unit, can be attained in no other way. If conditions were similar, power-driven tools would be necessary for grafting in the vegetable kingdom as well, in addition to the necessity for doing the work quickly. This last is an additional reason for employing motor-driven tools.

In plant grafting immobilization is effected in two ways, in addition to the

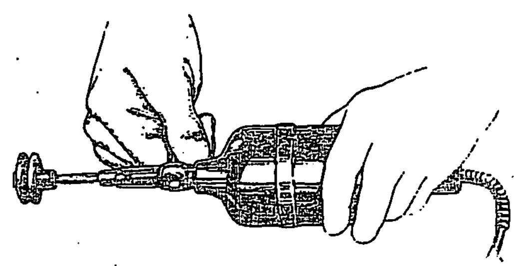

Figure 2: Twin circular saw chucked in the bone mill, held by the surgeon as in cutting an inlay from the shin bone or other available bone

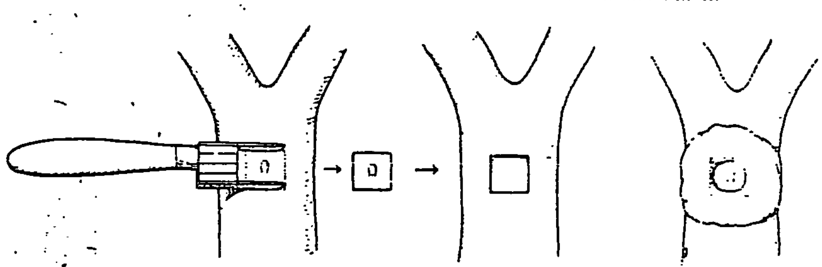

Figure 1: Left: Removing bark and bud with the double-bladed knife. *Center:* The bark removed from the host. *Right:* The finished graft, with paraffin

MACHINE TOOLS

the normal shape of the replaced bone, while the other fills out.

Recently we saw an operation of this kind, in color motion pictures, performed on a tubercular knee joint. With such speed that it seemed like opening a "zipper," the joint was completely exposed and the damaged bone was sawed away from the under side of the knee cap and the joint itself. Loss of the articulation then made necessary the rigid union of the upper and lower parts of the leg, and to accomplish this, two bone dowels were inserted, reaching through the top of the tibia and into the bottom of the femur. First the necessary holes were quickly made by means of twist drills and the bone mill—the patient, under total anaesthesia, being entirely unaware of the fascinating proceeding. Next, the two dowels had to be obtained and shaped. The shin bone was quickly exposed, with scarcely any bleeding, thanks to a tourniquet at the thigh. With the bone mill a pencil of bone about ½ of an inch square and eight inches long was quickly removed and cut in two. These pieces were rapidly fed into the bone mill, emerging as two neat, round dowels, which were then driven into the prepared holes. With no delay whatever the knee and leg were next flooded with antiseptic and closed.

The outstanding impression left by this spectacle was the speed and certainty with which skilled hands performed it. To perform work like this the surgeon must possess the mechanic's sure instincts for close, accurate work.—*The Editor.*

fixation provided by the accurate fit of the scion: the site of grafting is either bound with many layers of fabric or is covered with wax, or better, paraffin. These sealing substances serve as a sterile dressing as well, since they keep out fungi. If paraffin is used, immobilization is just as secure, and light—especially the ultra-violet—is allowed to penetrate to the wounded tissues and especially to the bud, which needs the ultra-violet for the metabolic activity of its chlorophyl.

I do not know the history of the double-bladed knife (Figure 1) which is used for plant-grafting, to ensure identity in size and shape of graft and graft-bed. I first saw it many years after I had designed the twin saw for bone grafting. Its use was demonstrated to me by the late Mr. W. J. Krome, in his citrus grove in Florida. Mr. Krome, after many years as a distinguished engineer, during which he supervised the construction of the Florida East Coast Railway in Key West, retired to indulge his interest in biology.

I did not design my twin saw (Figure 2) from this twin knife, but they were equally a response to the mechano-biophysiological demands of the problem. The twin saws may be regarded as a cutting calipers, since they ensure that the graft will accurately fit the graft-bed.

Plant-grafting and bone-grafting thus have the same objectives and are carried out according to the same fundamental ...nciples. In the plant the only force ...e counteracted is that of the wind, ... this only when the scion is of large diameter such as in the case of apple-trees. In bones, there is the pull of muscles, both involuntary and voluntary, and the exaggeration of the former by reflex from pain. Fixation and immobilization therefore present difficulties which must be met in a special way. It is necessary to consider bone, therefore, not only as a living tissue with an intricate circulation and metabolic function, but as a rigid piece of material which must be held in place with complete immobilization.

Union of graft with host, however much it may be affected by mechanical exactness, is dependent on the principles

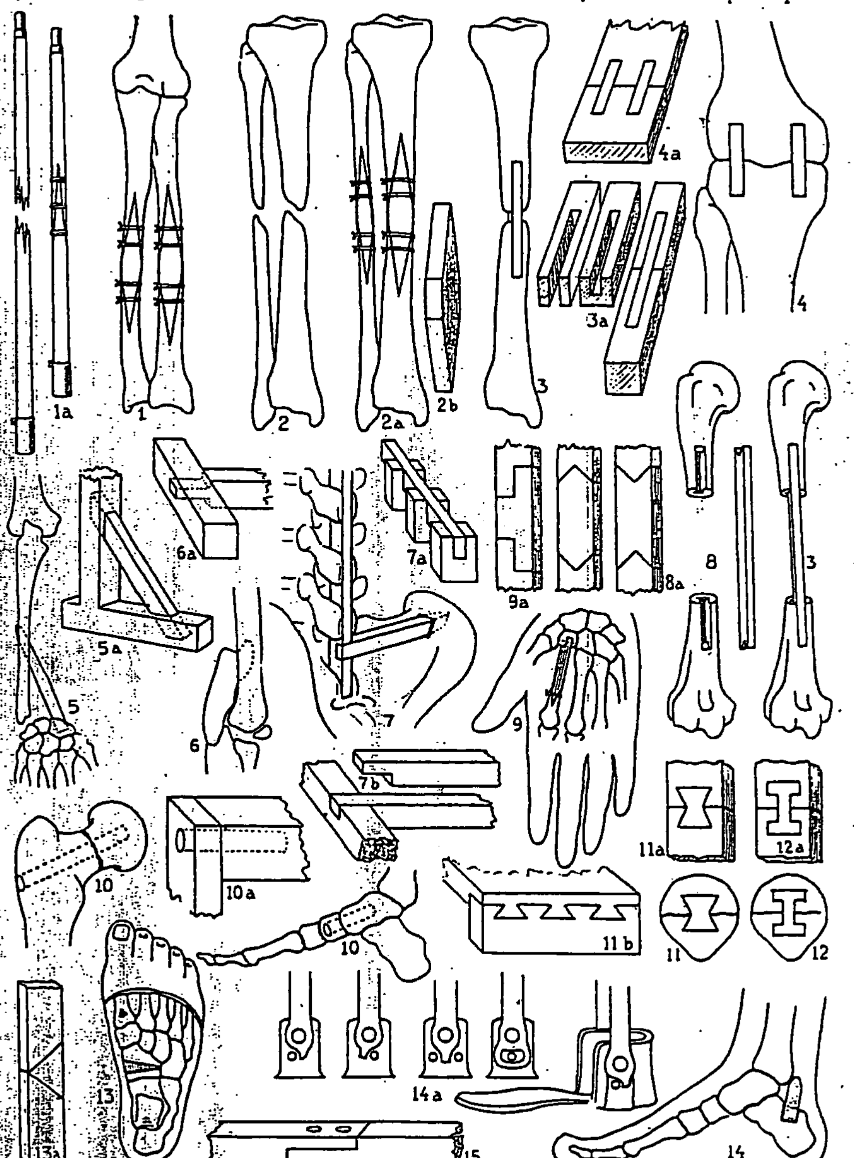

Figure 3: The fine joinery element in bone surgery—a group of self-evident analogies. Numbers 11 and 12 are keyed-in tension members in broken knee caps which will not join. No. 14 is a stop, made of the patient's own bone, to prevent the foot from dropping. No. 14a is the analogy—a brace made of metal. The bone surgeon must first of all be a born mechanic having marked aptitude

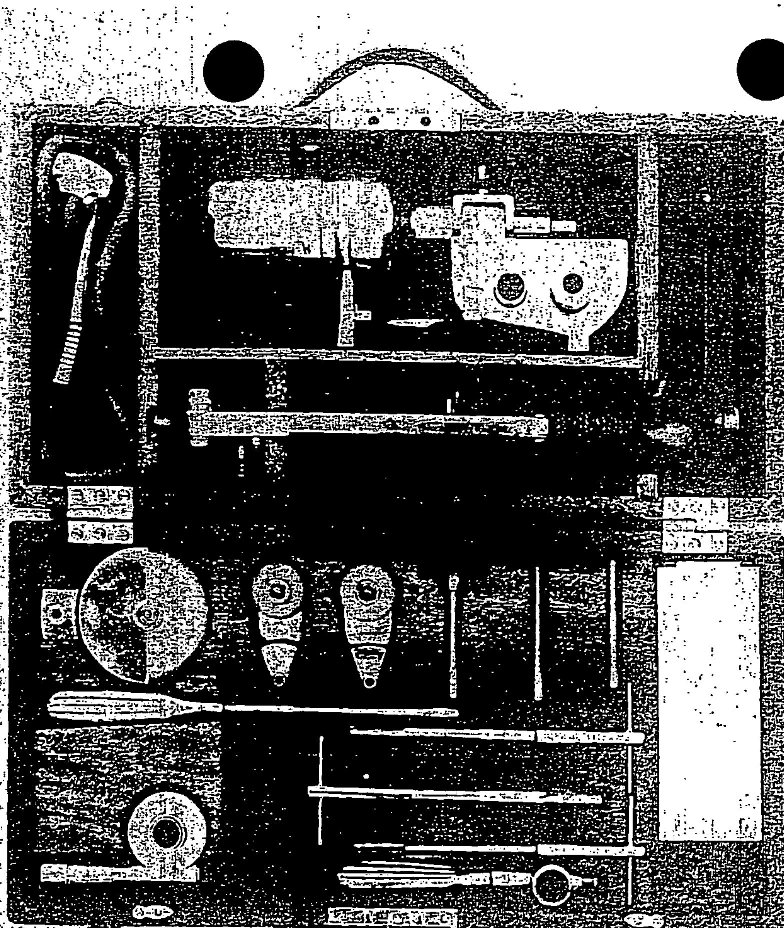

Figure 4: The bone mill (shown at top of the picture) in its carrying case, with its accessories. Here the apparatus shown in Figure 2 is attached to a base. This converts the hand mill into a fixed lathe, when needed thus. Note chocks on side, for tools used in shaping bone dowel pins at the operating table. In lower half are circular saws, also taps for tapping out holes in patient's bones to receive threaded bone pegs, as shown in Figure 6, at F'

of biology and physiology that govern the transplantation of tissue as a living, functioning structure. The graft lives if it is supplied sufficiently early and in quantity with blood from the host. Bony union with the host follows in the same way as it does after fracture, by a tissue bridge containing the first deposition of soft callus (soft bone material which is poured out, hardens and unites the bone) and then its impregnation with lime salts.

The graft, having been applied in a way most likely to favor its union with the host, is then influenced by those mysterious processes by which the graft remakes its structure, alters its shape and takes on added volume and strength, in order to accommodate itself to the demands of its new environment. That is, a graft of the general size of a lead pencil, and of any shaped cross-section, when implanted to take the place of a portion of the thigh bone, will take on the characteristics of the thigh bone shaft in every respect; that is, as to strength, size and shape of cross-section, external contour and internal architecture—it will even develop a marrow cavity.

For help with the mechanical problem, one must go to the joiner and study his various forms of mortise and how he selects each according to the mechanical demands of the situation (Figure 3).

My first application of the bone-graft was to the spine in Pott's disease. Since then, it has been used in grafting most of the bones in the body and for a variety of purposes, such as restoration of loss of bone from injury, disease, cancer, healing of broken bones which will not unite, cure of disease, correction of deformities, stabilization of joints, and so on.

The inlay graft in long bones is a perfect example of the ploughed-and-tongued joint, as well as of the application of like tissue to like. It is therefore a complete response both to the biological demands of comparative botany and physiology and to the principles of mechanics that guide the joiner.

The inlay graft (Figure 5) is applied principally to the broken long bones which fail to unite. In typical non-union, the ends of the fragments are avascular or anemic, circulation being deficient for a greater or lesser distance back from the region of the fracture. The bone is hardened and contains few, if any, active callus-forming cells. Its vitality, and hence its power of regeneration, is slight. A bone-graft inlaid into the fragment, reaching far enough back to tap the blood-supply and sources of nutrition and osteogenesis or bone formation in the healthy bone of the host, will bring to the zone of non-union forces which are of the same order as the reparative and osteogenetic power of recently fractured bone. The source of regeneration lies mostly in the soft-tissue structures that sheathe the bone and are enclosed in its medullary canal as well as upon the surface. Hence the graft and graft-bed are at best the full thickness of the bone cortex, so that like tissue may make contact with like, from marrow to periosteum. The vascular channels, especially the capillaries, in graft and host bone unite. Thus the graft obtains nourishment, not only for its own existence and subsequent growth and rearrangement, but for the nutrition of the avascular and impoverished ends of the fracture fragments.

ONE must not picture the graft as persisting in the form of a slender bridge between two fragments of sclerosed or hardened bone. The graft not only throws out callus and ossifies it, but responds to biological demands. It enlarges and thickens almost to any degree and takes on the structure of the host bone. More than that, the sclerosed fragments respond to the demands of restored function. Just as disuse brought about atrophy of the organic structures (vascular and cellular) in the useless fragments, so now restoration to usefulness and subjection to stress stimulate reconstruction of the fragments. Vessels grow in, the dense bone is absorbed and the original structure is eventually restored. It is again Wolff's law of stress, which is only one striking expression of the law governing the relation of structure and growth to function, whether it be in the animal or vegetable kingdom. This law of stress is omnipresent in all living supportive tissue. It determines that the diameter and strength of the trunk of a tree shall be larger than any other portion of that tree. By the same token, the contour, size and strength of the human skeleton are controlled by the stress demands incident to the part. This is also true of a bone-graft used to replace or repair a bone.

In the vegetable kingdom the conformation of the graft and its bed is always some modification of the inlay, whether it be the bud of the orange or the scion of the apple-tree, and so on. In the case of the bone-graft, besides a contact with host tissues that insure its living, there arises a multitude of mechanical demands which would tax

the ingenuity of the most [redacted] boss carpenter, joiner, cabinet-[redacted] or machinist.

However difficult and exacting the piece of bone cabinet-maker work may be, it is necessary to add a still further fact that is true of all surgical problems—the all-important factor of time. The patient is under an anæsthetic, the tissues are open and exposed to the devitalizing influence of the air, instrumentation, and so on. Every instrument or tool must be made sterile by boiling. Bone, being always surrounded by muscles or other soft tissue, is never favored by circumstances comparable to those surrounding material being worked upon in the shop. Because of the hardness, brittleness, and knurly character of bone, and the inability of the surgeon to avail himself of the advantages of the anvil or vise to fix and hold the bone which he cuts, the chisel and mallet are at a disadvantage. Rotary, electrically-driven tools are thus a great advantage.

THE surgeon's difficulties, above indicated, have been largely overcome by making available to him the great advantages of the various automatic cutting tools, electrically-driven. In fact, the writer has designed a bone mill along these lines (Figures 2, 4), which enables the surgeon to shape the bone at the operating-table, under surgical sterile conditions, with the same variation and facility that are possible in shaping wood in the carpentry shop or metal in the machine shop. The various motor-driven male cutters (Figure 6, *B*, *F*) shape parts that fit accurately into other parts shaped with corresponding female cutters (Figure 6, *G* to *P*), however quickly the work is done. With this surgical mill, inlays of every variety are rapidly accomplished. These vary from straight inlays to crosses, double crosses, T's, irregular shapes, and so on, of a great variety. The cutting tool for this work is the twin saw, which is as adjustable as the calipers, and in fact is used as a cutting calipers. In this instance the twin saw serves as both the male and female cutter.

The graft may be shaped into any sized peg desired, by means of the lathe attachment. A close fit is assured by selecting the appropriate sized drill (Figure 6, *O*, *P*) when making the hole for such peg grafts. It is important that the fit should be that of the accuracy of a glass-stopper in a bottle, and not that of a cork-stopper, or a square peg in a round hole. Compression may kill bone cells, either in graft or host tissues, or close blood-vessels that should otherwise bring nourishment to the living graft cells. If, by chance, a screw is needed for the human reconstruction, threads are cut upon the peg by pushing it through an electrical rotating die (Figure 6, *F*) which is incorporated in the mill. The drill hole which is to receive the screw is threaded by the corresponding sized tap.

The successful living bone-graft is based upon a tripod of exacting conditions and environment as to mechanics, physiology, and biology. The fit must be exact for a double purpose, to assure fixation and immobilization of the graft as well as the parts it is to repair. This makes for the early and profuse vascularizing of the graft by the penetration into it of blood-vessels from the host tissues.

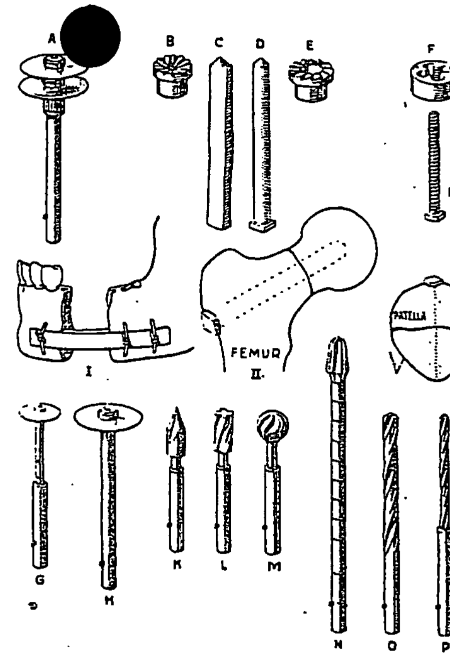

Figure 6: A is the twin saw. Speed 3000 r.p.m. *B* is a miller for pointing the end of a bone dowel, as in *C*. *D* is a dowel after rounding in *E*, and *F* is a die for threading a bone screw like *F'*. Dowels and screws like these are made on the spot from bone removed from the patient's own body and inserted elsewhere in it—all in one minute by the clock. *I* is a jaw bone, with an inlay taken from the shin. Not only does the living bone unite with the jaw bone, but it grows, filling in the whole gap. Note ordinary machinist's twist drills *O*, *P*, for boring holes for dowels

The query may arise, is this exactitude necessary? The answer is, the proof of the pudding is the eating. By using such methods, many successful results have been secured where operative failures up to 14 have preceded in a single case.

Reparative operations are often done long after the loss of bone, when the urge to repair has nearly or completely ceased. The surgeon must liken himself to a cabinet-maker who finds that he is running short of glue, and then must make his fits all the more exact, so that the glue will be sufficient. In the case of bone, callus is the glue.

The inherent biological urge to repair, which follows an injury to bone, diminishes to a varying degree as time elapses. The fresh cuts made in the bony elements at the operation tend to revivify this to a degree, but it always devolves upon the surgeon to select bone for reparative purposes, of the highest inherent callus-forming potentiality. It is well known that tibial bone has a higher degree of bone forming capability than bone from the spinal column, hence the use of the shin bone for graft material.

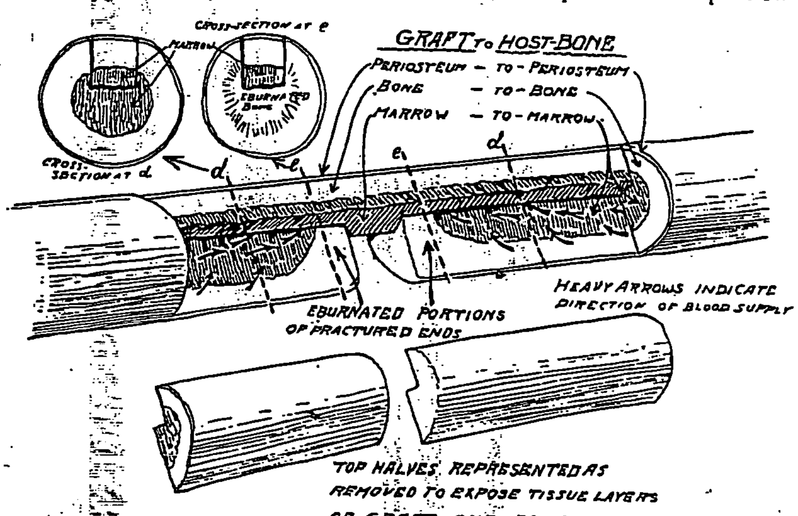

Figure 5: Showing the principle of an inlay graft. First note old, stubborn, unclosed gap between ends of bones. Next, the long, slender, square piece of shin bone which has been set across it as an inlay. The two pieces in the foreground are not a part of the graft but are merely shown here *as if* removed, in order to permit showing the situation inside of a bone. "Eburnated"=hard

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(54) Wirbelkörperimplantat.

(57) Als Implantat für Wirbelsäulen wird eine Scheibe (11) vorgeschlagen, die alleine oder zu mehreren gestapelt (11 bis 14) zwischen Wirbelkörper einsetzbar sind. Einzelne Scheiben werden nach Bedarf von einem Strang abgeschnitten, wobei die Scheibendicke dem Einzelfall genau angepaßt werden kann. Diese Implantate eignen sich insbesondere für Halswirbel sowie als Ersatz nach der Entfernung von Bandscheiben. Für die Bildung eines Implantats aus mehreren übereinandergestapelten Scheiben kann ein entsprechendes Sortiment von Scheiben bereitgestellt werden, die sich sowohl im Durchmesser als auch in der Höhe unterscheiden. Für den jeweiligen Anwendungszweck werden demzufolge Scheiben mit entsprechender Dicke ausgesucht und zusammengesetzt, so daß sie insgesamt die erforderliche Höhe des Implantats ergeben. Verschraubungen und insbesondere längere Handhabungen im eingesetzten Zustand des Implantats sind bei dem erfindungsgemäßen Implantat nicht erforderlich.

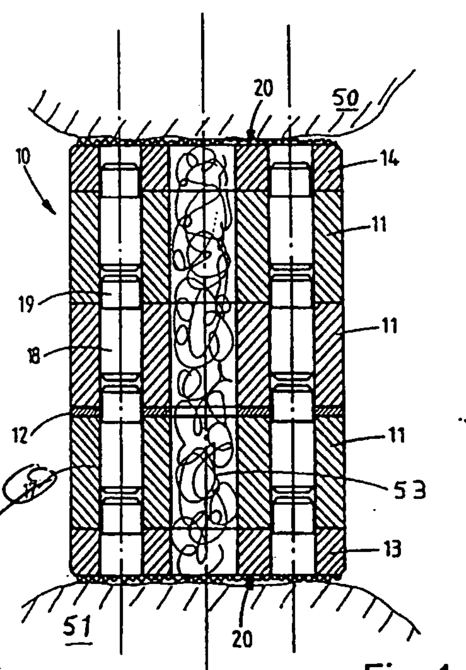

Fig.1

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Auch die Scheibenpackungen können als Ringscheiben ausgebildet werden, wobei der Hohlraum zur radialen Verankerung der Ringe mit Knochenmaterial oder -zement ausgefüllt werden kann. Vorteilhaft ist es, wenn der Innenmantel der Ringscheiben unregelmäßig ist oder geometrische Unregelmäßigkeiten aufweist. jede Abweichung von der kreiszylindrischen Form dient zur drehsicheren Verankerung der aufgestapelten Scheiben, wenn der Hohlraum der Ringscheiben mit einem härtenden Material ausgefüllt wird.

Für den sicheren Halt des als Scheibenstapel ausgebildeten Implantats zwischen den angrenzenden Wirbelkörpern werden Endscheiben mit einer rauhen Stirnseite vorgesehen. Die Rauhigkeit kann durch eine strukturierte Oberfläche, herausragende Spitzen, Wellen und dergleichen erzeugt werden.

In jeder Ausführung ist es möglich, die Scheiben zu einer soliden Einheit miteinander zu verkleben, z.B. mit PMMA-Zement, wenn erforderlich oder zweckmäßig.

Die Scheiben werden vorzugsweise aus einem kohlenstoffaserverstärkten Kunststoff (CFK) hergestellt, wobei die Verankerungsmittel je nach Ausgestaltung des Implantats aus demselben oder einem anderen Material bestehen können. Die Herstellung des gesamten Implantats aus CFK hat den Vorteil, daß das Implantat keine Streuung von Strahlen bewirkt, so daß die Wirbelsäule und das angrenzende biologische Gewebe auch nach dem Implantieren eines Wirbelkörperersatzes mit allen bildgebenden Verfahren (CT, MR) untersucht werden kann

Bekannte Wickeltechniken lassen sich zur serienmäßigen Fertigung der Implantat-Elemente anwenden. Die Ringscheiben können beispielsweise mittels einer Flechtmaschine, die zusätzlich mit unidirektionalen Fasern (UD) bestückt ist, hergestellt werden. Mittels eines Stabdornes, der durch das Flechtauge gezogen und mit UD-Fasern und Flechtwerk umlegt wird, wird ein Faserverbundrohr in einem Arbeitsgang hergestellt, von dem dann die Ringscheiben abgeschnitten werden. Der Stabdorn ist vorzugsweise aus dem auch als Trennmittel verwendbaren PTFE (Polytetrafluorethylen). Der Stabdorn kann dabei ein Vieleck als Querschnitt haben oder über die Länge Nuten und/oder Erhebungen aufweisen, wodurch im Faserverbundrohr bzw. in den Ringscheiben die für die drehsichere Verankerung dieerforderliche Innenmantelgeometrie direkt bei deren Herstellung gebildet wird.

Auch Wickelverfahren unter Anwendung von Fasern oder Fasergelegen erlauben fertigungstechnisch einfache und für Serienfertigung geeignete Herstellverfahren. Es können einheitliche Streben für die Einzelscheiben und die Scheibenpackungen konzipiert werden.

Die Erfindung wird anhand von in der Zeichnung schematisch dargestellten Ausführungsbeispielen näher erläutert. Es zeigen:

Figuren 1 und 2
ein erstes Ausführungsbeispiel,
Figuren 3 und 4
ein zweites Ausführungsbeispiel,
Figuren 5 bis 8
je ein weiteres Ausführungsbeispiel.

Der Erfindung liegt der Gedanke zugrunde, daß der Chirurg an Ort und Stelle direkt nach Kenntnis der tatsächlichen Abmessungen den Wirbelkörperersatz zusammenstellt, ohne die Hilfe eines Prothesentechnikers. Dazu wir ein Vorrat von Strängen unterschiedlicher Durchmesser und/oder eines Sortiments von Implantatkomponenten unterschiedlicher Durchmesser und Höhen gehalten, so daß für den jeweiligen Fall entweder eine entsprechende dicke Scheibe aus dem entsprechenden Strang herausgetrennt oder die entsprechende Anzahl von Komponenten mit entsprechenden Abmessungen herausgeholt und zusammengesetzt zu werden braucht, ohne Schraubjustier-oder andere Handgriffe vornehmen zu müssen. Die Auswahl der Scheiben nach ihrer Höhe im letzten Fall kann mittels eines Rechners erfolgen.

Die Grundlage eines zusammengesetzten Implantats besteht im Aufstapeln von vorgefertigten Scheiben, wobei diese Scheiben eine runde, mehreckige oder unregelmäßige Außenkontur haben können. Es können volle Scheiben oder auch Ringscheiben als Komponenten verwendet werden. Es werden Scheibensätze mit unterschiedlichen Durchmessern benötigt, wobei jeder Satz eines Durchmessers mit Scheiben unterschiedlicher Höhe bestückt ist. Steht der Durchmesser des einzusetzenden Implantats fest, so werden in dem entsprechenden Scheibensatz noch die entsprechenden Höhen ausgesucht, so daß nach dem Zusammensetzen der gewählten Scheiben sich die erforderliche Implantathöhe ergibt.

Um das Sortiment bezüglich der Scheibenhöhe möglichst klein zu halten, können beispielsweise wenige hohe Abmessungen vorgesehen werden, die mit niedrigen Scheiben, z.B. millimeterdicken Scheiben, entsprechend ergänzt werden.

In Fig. 1 ist ein Ausführungsbeispiel gezeigt, bei dem ein fertiges Implantat 10 aus drei dickeren Scheiben 11, einer dünnen Scheibe 12 und zwei Endscheiben 13 bzw. 14 zusammengesetzt ist.

Wie in Fig. 2 dargestellt ist, bestehen die Scheiben 11 bis 14 aus runden Ringscheiben mit einer Innenbohrung 15 und jeweils vier regelmäßig auf die Ringscheibe verteilten Bohrungen 16. In diese Bohrungen 16 werden Verankerungsstifte 17 eingeführt. Gemäß der Ausführung nach Fig. 1 sind die Stifte 17 mit ihrem jeweils einem Ende 18 mit einer Scheibe 11, 13 verbunden, während sie mit dem anderen Ende 19 in die Bohrung einer näch-

pern feststellbar ist, wird mittels dieses Wertes im Rechner die Zusammensetzung der Scheibenhöhen für das Implantat errechnet, herausgesucht und zusammengesetzt oder mittels eines genau einstellbaren Werkzeugs die Scheibe vom Strang abgetrennt. Die angrenzenden Wirbelkörper werden etwas auseinandergezogen und das im Baukastensystem zusammengesetzte Implantat bzw. die Scheibe zwischengelegt. Außer dem Plazieren des Implantats sind keine weiteren Handgriffe bezüglich des Implantats notwendig. Außer der Implantathöhe variiert auch der Durchmesser des Implantats. Das Scheiben- und/oder Strangsortiment ist daher auch nach Querschnitten zu bestücken.

In Fig. 8 ist schließlich ein hohler Strang 50 unregelmäßiger Konfiguration gezeigt, der aus 1 bis 20 Flechtwerken 51 gebildet ist. Ein nicht gezeigter Dorn wird entsprechend oft durch das Ringfadenauge einer Flechtmaschine gezogen und dabei mit entsprechend vielen Flechtwerken und Matrixmaterial überzogen. Mit Trennscheiben werden an Trennlinien 52 die Scheiben 53 für ein Implantat oder Implantatelement herausgeschnitten.

Patentansprüche

1. Implantat für die Wirbelsäule, bestehend aus mindestens einem steifen Element, dadurch gekennzeichnet, daß das Implantat aus mindestens einer Scheibe (11 bis 14, 21, 35, 45, 53) besteht, die direkt zwischen zwei angrenzenden Wirbelkörpern zwischenlegbar ist und je nach Wirbellage parallele oder zueinander im Winkel stehende Auflageflächen hat.

2. Implantat nach Anspruch 1, dadurch gekennzeichnet, daß die Scheibe als Ringscheibe (35, 45, 53) mit regelmäßigem oder unregelmäßigem Umfang ausgebildet ist, und daß der Innenumfang der Scheibe einen vieleckigen oder unregelmäßigen Querschnitt hat.

3. Implantat nach Anspruch 1 oder 2, dadurch gekennzeichnet, daß die Auflageflächen der Scheibe (14, 35, 53) Rauhigkeiten, Porenwelligkeiten oder andere Unebenheiten aufweisen.

4. Implantat nach Anspruch 1, dadurch gekennzeichnet, daß die Auflageflächen der Scheiben (14, 35, 53) herausragende Spitzen (20) aufweisen.

5. Implantat nach einem der vorhergehenden Ansprüche, dadurch gekennzeichnet, daß die Scheibe (45) Kanäle (46) aufweist, in die Knochenzement oder Knochenmaterial einbringbar ist.

6. Implantat nach einem der vorhergehenden Ansprüche, dadurch gekennzeichnet, daß die Scheibe (11 bis 14, 2135, 45, 53) aus faserverstärktem Kunststoff besteht und im Wickelverfahren oder ausaufgerollten Fasermatten hergestellt ist.

7. Implantat nach einem der vorhergehenden Ansprüche, dadurch gekennzeichnet, daß die Scheibe (53) aus einem Strang (32, 33 bzw. 50) geschnitten ist.

8. Implantat nach Anspruch 7, dadurch gekennzeichnet, daß der Strang (32, 33 bzw. 50) aus unidirektionalen Fasern (32) und/oder Flechtlagen (33, 51) besteht.

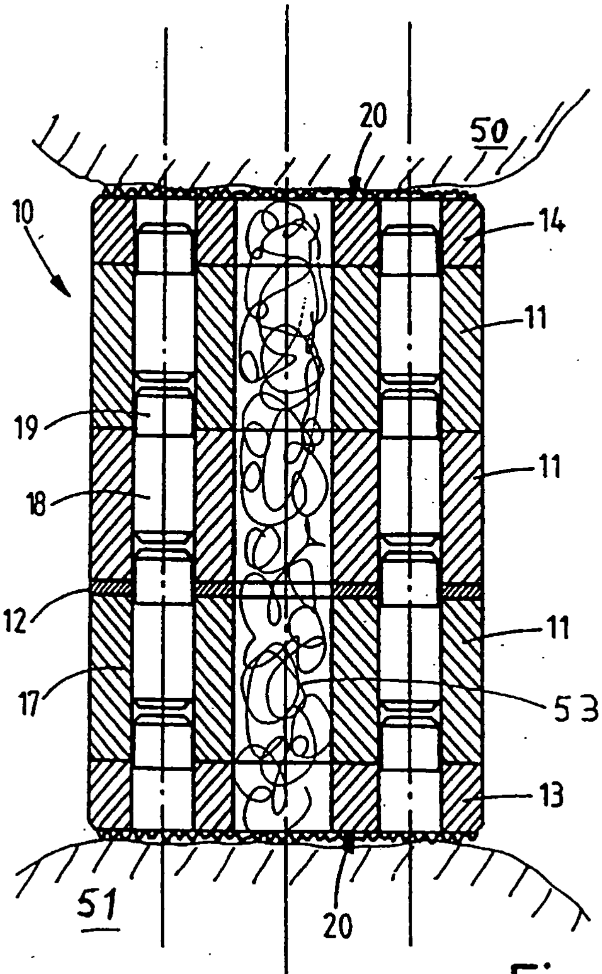

Fig.1

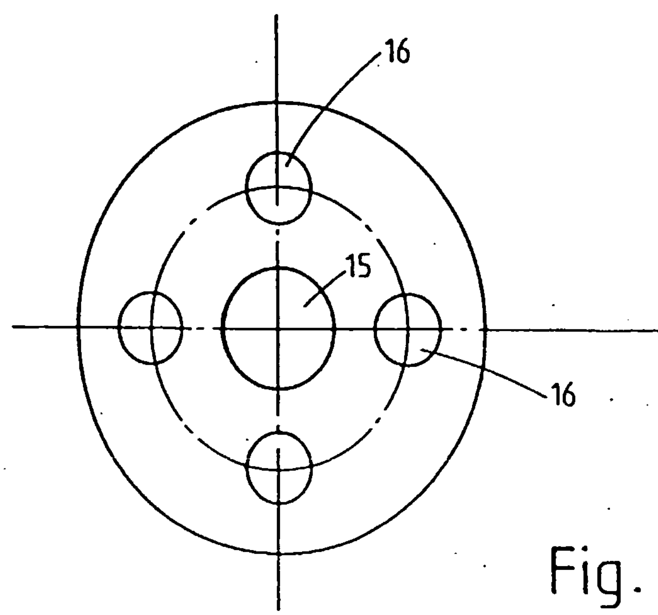

Fig.2

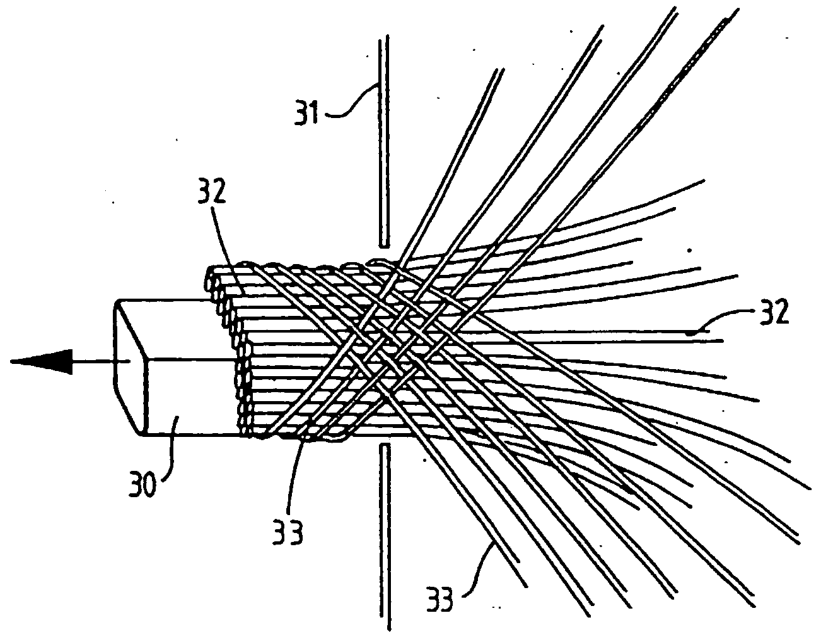

Fig. 5

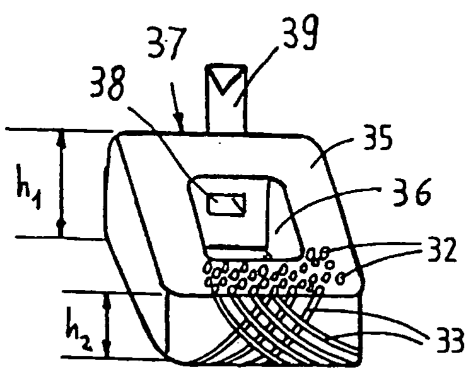

Fig. 6

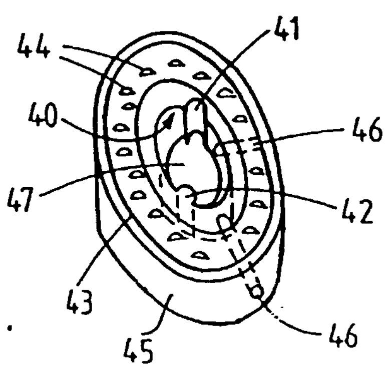

Fig. 7

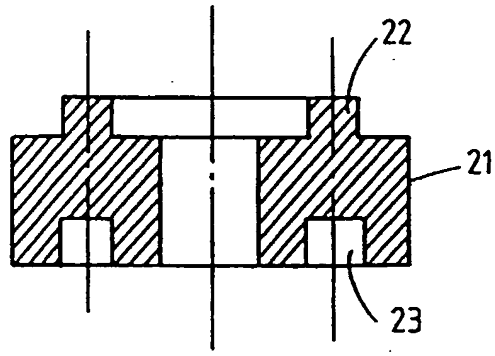

Fig. 3

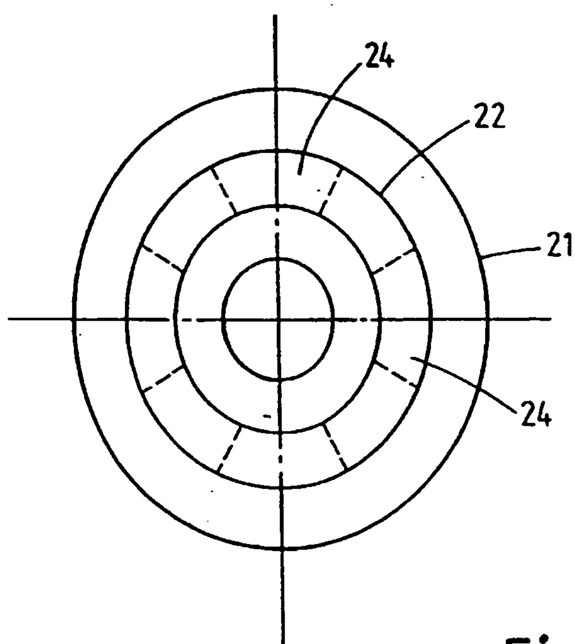

Fig. 4

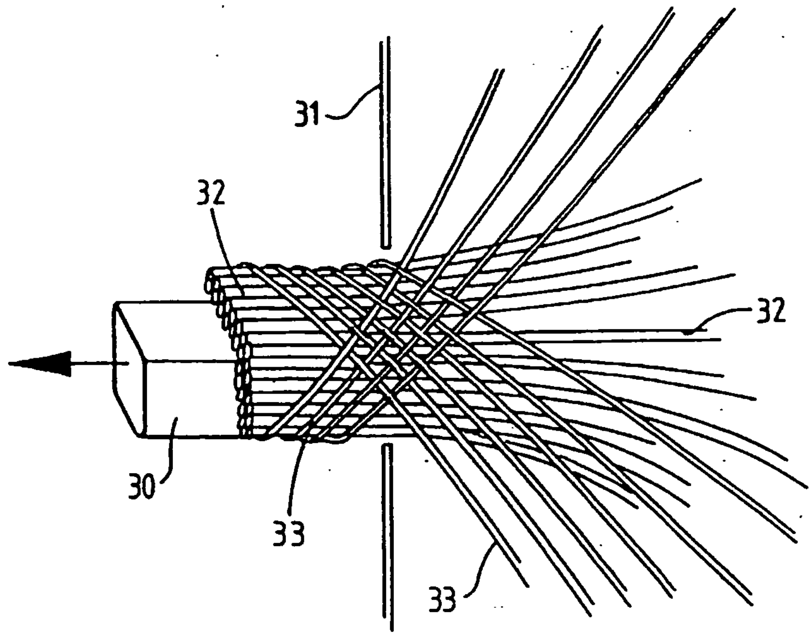

Fig. 5

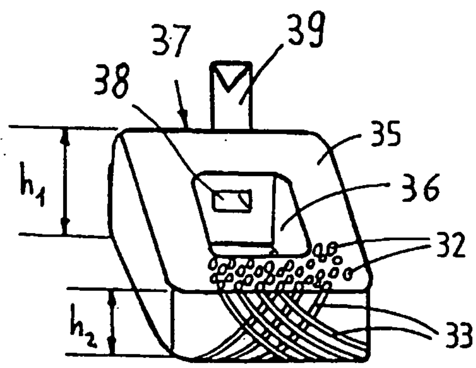

Fig. 6

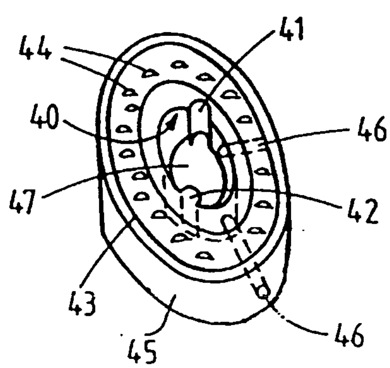

Fig. 7

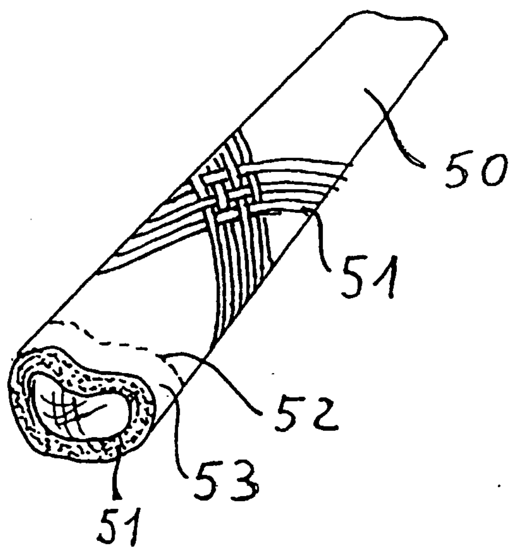

Fig.8

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Designated high contracting parties to regional patent conventions: CH DE FR GB IT LI
Applicant; MAN Ceramics GmbH·
Inventor: Wolfgang Siebels, Spitzwegstraße 17, D-8360 Deggendorf and Rudolf Ascherl, Türkenstraße 53, D-8000 Munich

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[Title in German of the object of the invention:]
Wirbelkörperimplantat

INTRAVERTEBRAL BODY IMPLANT

The invention pertains to an intravertebral (intraspinal) body implant for vertebral (spinal) columns consisting of at least a rigid element.

Intravertebral bodies have different size along a spinal column, and vary from patient to patient. Therefore, when an

intravertebral body is substituted by an implant, it is necessary that the implant is matched to the effective size of the interval between the adjacent intravertebral bodies.

In order for an allowance to be made for this interval, implants were developed (DE 30 23 942 C3), which essentially consist of two parts, which are connected to one another by means of a threaded connection, and whose axial height can be changed by rotation, or which can be matched to the interval between the intravertebral bodies. By means of transverse bolts or other means of anchoring, the two parts are anchored in a way, which is resistant to torsional stress or prevents a rotation. Therewith, by means of a single embodiment an entire range of intervals can indeed be covered, however the adjustment in height takes relatively much time in the case of a fine thread.

An implant of the generic kind, which rectifies this imperfection, is known from the WO 90/00037, which implant is inserted solely between two vertebrae by means of a tool. However, the approximately rectangular implant is assembled out of intricate individual parts.

Therefore, the objective to develop an implant of the kind mentioned at the outset, which can rapidly be implanted and which - from the standpoint of manufacturing engineering - can also easily be manufactured for a multiplicity of overall dimensions, forms the basis of the [proposed] invention.

In accordance with the invention, the set objective is

achieved with the help of the features, cited in claim 1.

Not only is a disk easily inserted into a spinal gap but it can also be manufactured in such a way that it can very easily and dimensional correct be matched to a certain case of application. For example, in the case of a specific application, it is thus possible that first of all the disk is cut out of a prefabricated solid or hollow strand, sterilized, or separated in sterile state with the help of a sterile grinding tool and sterile water. By using a coarse-grained grinding, respectively cutting tool, a rough surface, promoting the growth process, is imparted to the sectional areas of the implant [spinal] disk, which form the support for the intravertebral bodies.

Basically, the use of a disk of any configuration, be it of round, polygonal, irregular contour, is possible. Also, the inner contour of an annular disk can be created as occasion demands.

The contact surface of a disk, which is being used for the adjacent intravertebral bodies, is designed as structured for the promotion of the growth process, and is selected as being coarse, or running in different directions. Anchoring means in the form of projecting tips or spikes are used for the immediate securing of the prosthesis after the implantation takes place.

The disk-shaped implant is preferably made of fiber-reinforced plastic [FRP]. In accordance with a preferred embodiment of the invention, in order to produce a single-piece implant, the disk is cut out of a hollow strand, which consists

of a multiple number of braiding layers [plaiting layers]. The braiding layers, are wound up one after another on a correspondingly shaped mandrel [arbor], preferably on a mandrel, having rectangular cross-section and rounded corners, directly in a braiding machine. The disks are cut off with the desired height, which can vary over the disk. Implants of this kind are characterized in that they can be manufactured in an extraordinarily easy way, in which the fiber orientation equally imparts an optimal rigidity and strength to the implant.

In accordance with yet another embodiment of the invention, two or more disks are assembled, in order for an intravertebral body implant to be produced. In that case, a stock of an assortment of disks, having different height and diameter, is kept, available at hand. For the purposes of an implantation, the interval between the vertebrae is measured, and correspondingly thick, respectively high, disk of the assortment are combined together in such a way, that they have the desired vertical dimension in their entirety. The selected disks - they consist of parts of analogous shape, only having different height - are stacked one above another, in accordance with the modular principle, and are inserted as ready-made implant between the intravertebral bodies, which - to this end- are slightly pulled apart. Also, in this case, after the insertion of the implant, a regulation or adjustment of the latter inside the patient body is not required.

With the help of a computer, the disks' heights, which are to be combined, are instantaneously determined so that a minimal time input is required between the spinal interval measurement and the reception of the insertable implant. The radial anchoring, and the anchoring, preventing a rotation and resisting the torsional stress, of the assembled disks, can be mastered in a multifarious way.

In accordance with an embodiment of the invention, the disks have aligned boreholes, into which anchoring pins or studs can be inserted. In that embodiment, the disks are radially connected to one another, and also in such a way that they resist the torsional stress [i.e. possess torsional strength], and cannot rotate. Moreover, from a manufacturing engineering standpoint, the manufacturing of the disks is very easy.

Another possibility consists in that the disks are directly produced as having molded anchoring means, such as, e.g., groove and tongue, pin [stud] and boreholes.

Also, the disk packages can be designed as annular disks whereby the hollow space is filled with bone material or bone cement for the purposes of a radial anchoring of the rings. It is advantageous when the inner jacket of the annular disks is irregular, or has geometrical irregularities. Each deviation from the circular cylindrical shape is used for a torsionally resistant anchoring of the stacked disks when the hollow space of the annular disks is filled up with a hardening material. In

order for a reliable support of the implant - which is designed as a disk stack - to be achieved between adjacent intravertebral bodies, end-disks are provided, having a rough frontal side. The roughness can be generated by means of a structured area, projecting tips, undulations, and similar.

In each embodiment, it is possible to glue the disks with one another into a solid unit, e.g., with the help of PMMA* cement, if required,or if functionally feasible. [*Translator's note: PMMA = polymethyl methacrylate].

Preferably, the disks are made of a carbon-fiber reinforced plastic (CFP) whereby the anchoring means - according to the design of the implant - can consist of the same, or another material. The manufacturing of the entire implant of CFP has the advantage that the implant does not bring about any scattering of rays, so that the spinal column and the adjacent biological tissue can also be examined after the implantation of a spinal-column replacement with the help of all image-producing methods (CT*, MR*) [*Translator's note: CT = charge-transfer (absorption band or electron-transfer band); MR = magnetic resonance).

Known winding techniques may be used for series-manufacturing of the implant elements. For example, the annular disks ["washers"] can be made with the help of a braiding machine, which is additionally outfitted with unidirectional fibers (UD). By means of bar-shaped mandrel, which is pulled

through the braid eyelet, around which there are laid UD-fibers and braiding, a bonded-fiber tube is generated in a single run, from which the annular disks are afterwards cut off. The bar-shaped mandrel is preferably of PTFE (polytetrafluoroethylene), which is also used as mold release agent. At the same time, the bar-shaped mandrel can have a polygonal cross-sectional area, or grooves all over the length, and/or elevations, as a result of which the inner-jacket geometry, required for the torsionally-resistant anchoring, can directly be formed in the bonded-fiber tubes, respectively in the annular disks, over the course of their manufacturing.

Also, winding methods using fibers or fiber-woven fabrics allow a manufacturing process, which is simple from the standpoint of manufacturing engineering, and suitable for series-manufacturing. Unified struts for the individual disks and the disk packages [packings] can be designed.

The invention is elucidated in greater detail by means of exemplified embodiments, diagrammatically represented in the drawing, wherein

Figs. 1 and 2 show a first exemplified embodiment,

Figs. 3 and 4 show a second exemplified embodiment

Figs 5 thru 8 show another exemplified embodiment, each.

The notion that the surgeon directly assembles the spinal body substitute [replacement set] on the very spot by knowing the actual overall dimensions and without the help of a prosthesis

technician, forms the basis of the invention. To this end, a stock of strands, having different diameter and/or a supply of an assortment of spare implant components, having different diameter and height, is maintained so that for each relevant case either a corresponding thick disk needs to be separated from the relevant strand, or the relevant number of components, having relevant dimensions ought to be taken out, and assembled without threaded [screw] adjustments or other types of handling. In the last case, the selection of the disks according to their height can take place by means of a computer.

The base of an assembled implant consists in the stacking of prefabricated disks whereby these disks can have a round, polygonal or irregular outer contour. Solid disks or also annular disks can be used in their capacity as components. Disk assortment sets, having different diameters, are necessary whereby each assortment of a diameter is outfitted with disks, having different diameter. If one is absolutely certain about the diameter of the disk to be used, the corresponding heights are yet to be selected within the framework of the corresponding disk batch [assortment set] so that after the selected disks are assembled, the required implant height is thus produced.

For example, in order for the assortment with respect to the disk height to be maintained as small as possible, few high dimensions can be provided, which are correspondingly supplemented with lower disks, e.g., having a thickness of

several millimeters.

Fig.1 shows an exemplified embodiment, in which a ready-made implant 10 is assembled out of three thicker disks 11, a thin disk 12, and two end-disks 13 and 14.

As diagrammatically represented in Fig. 2, the disks, 11 thru 14, consist of round annular disks, having an inner borehole 15, and four boreholes 16, respectively, which are equitably distributed over the annular disk. Anchoring pins [studs] 17 are introduced into these boreholes 16. In accordance with the embodiment, depicted in Fig. 1, the pins 17 are connected with one of their respective ends 18 to a disk 11, 13 while they protrude with the other end 19 into the borehole of the subsequent disk 11. In this embodiment, an end-disk 14 is designed without pin [stud]. In an analogous way, the thin disks 12 have solely boreholes 16.

Self-evidently, it is also possible to produce the pins as structural components separated from the disks 11 thru 14 so that the pins are introduced into the boreholes 16 only when the assembly of an implant 10 takes place.

Instead of pins, groove-and-tongue systems can also be provided as anchoring means in each possible configuration.

Fig. 3 shows an exemplified embodiment, in which the disks 21 are provided with an annular [ring] spring 22 on one of the frontal sides whereas, on the other frontal side, they are provided with an annular groove 23, aligned with the annular

spring 22. In order for an anchoring to be also achieved in the torsional direction, spring segments 24 can be provided instead of the annular [ring] springs 22, as indicated by the dotted line in Fig. 4, which spring segments engage into corresponding grooved segments of the next disk.

In the diagrammatically represented exemplified embodiments, there were shown round disks, having a circularly symmetric distribution of the anchoring elements. It is self-evident that any asymmetric arrangement of the anchoring elements as well as of any outer contour of the disks is possible as long as the latter are in agreement with the contour of the intravertebral bodies.

From the standpoint of manufacturing engineering, annular disks or solid disks can easily be manufactured of any biologically compatible material because they are not bound to a particular shaping. The shape can even partially be matched to the manufacturing method. Manufacturing methods, which are adequate for the series-manufacturing are winding or pulling of bonded-fiber tubes, out of which the disks are sawn off, cut off, or separated, either as individual element or as elements for the disk packings [packages], described above. In the winding method, fibers or fibrous mats are used in accordance with known methods. In the braiding method, as depicted in Fig. 5, a correspondingly shaped bar-shaped mandrel 30, e.g., having a rectangular cross-section, is passed through a thread eyelet [guide] 31, and, in

doing so, it is surrounded with bundles of longitudinally directed, unidirectional [UD] fibers 32, impregnated with matrix, as well as with outer braiding fibers 32. After the solidification of the matrix, annular disks 35 are separated out of the bonded-fiber tube thus produced, whereby the mandrel is removed prior to or after the separation of the annular disks. The strand, which is designed as bonded-fiber tube, is used for the manufacturing of individual disks as well as for the manufacturing of a disk package, as depicted in Fig. 1.

When needed, individual disks 35 are separated as wedge-shaped ones (Fig. 6, ($h_1 > h_2$). In the neutral area 37. there can be provided openings 38, which are used to engage the implantation tools and fixation means, such as staples [cramp irons; clams; or clips] 39.

The hollow space 36 can be filled up with extraneous bone material, or with patient's own bone material, or with bone cement, which can also be introduced through the opening 38. When the disks are assembled, the bone cement is also used for the anchoring of the disks in the radial direction, and - due to the non-circular symmetric inner cross-section 36 - in the torsional direction as well. Instead of the rectangular inner cross-section, any other configuration - save the circular shape - can be selected, in order for a free rotational motion between the disks to be precluded.

Fig. 7 shows a shape, having a cylindrical inner jacket 40, which is outfitted with an elevation 42 for torsional anchoring.

If need arises, the disks or annular disks are provided with a starter foil 43- as shown in Fig 7 - surrounding adhesive cartridges 44. When two disks 45 for the formation of the implant are placed one above another, and axially compressed, the adhesive cartridges 44 burst open, so that the adhesive is distributed between the disks 45, and connects the disks with one another. The adhesive connection can be used as single connection or supplementarily to the aforementioned anchoring means.

In the embodiment in accordance with Fig. 7, there are shown additional boreholes 46, which are radially guided through the annular disk 45. They are used for the introduction of the bone cement or bone material into the hollow space 47.

On their free frontal end, used as the support for the spinal bones, the end-disks 13, 14 of an implant 10 have a surface 20, which is rough, structured, or provided with discrete elevations. In interaction with the adjacent intravertebral bodies 50, 51, which are pressing against the implant 10, the said elevations should guarantee the anchoring inside the spinal column, and be used as growth help. As described above, bone cement or material 53 can be pressed - if need arises - through a non-diagrammatically represented radial borehole into the inner borehole 15 up to the adjacent intravertebral body 50, 51. In the case of a single-disk implant, both sides are correspondingly

designed. A rough surface can be directly formed within the framework of the separation process from strand by using a coarse-grained cutting tool.

The implantation of an intervertebral disk substitute and/or an intravertebral fibrocartilage [intravertebral ligament; intervertebral cartilage] of this kind is not subject to any system-specific problems. If the surgical step has gone so far that the interval between the adjacent vertebral bodies can be adjusted, the assembly of the disk-heights for the implant is calculated in the computer with the help of this value, selected, and assembled, or with the help of a precisely adjustable tool, the disk is separated from the strand. The adjacent vertebral bodies are somewhat pulled apart, and the implant, respectively the disk, assembled within the framework of the modular method, is inserted. As far as the implant is concerned, no additional manipulation procedures or handling are necessary save for the placement of the implant. Besides the implant height, the diameter of the implant also varies. Hence, the disk and/or strand assortment is also to be supplied according to cross-sectional areas.

Finally, in Fig. 8, there is shown a hollow strand 50, having an irregular configuration, which hollow strand is formed out of 1 to 20 braidings 51. A mandrel, which is not diagrammatically represented, is often pulled through the annular thread eyelet of a braiding machine, and, in doing so, lined with

many braidings and matrix material, respectively. With the help of separating disks, the disks 53 for an implant or implant element, are cut out at separating lines 52.

Patent Claims

1. Implant for spinal columns, consisting of at least a rigid element, characterized in that the implant consists of at least a disk (11 thru 14, 21, 35, 45, 53), which can be directly inserted between two adjacent vertebral [intravertebral] bodies, and according to the spinal position has parallel contact surfaces [support surfaces] or contact surfaces, which are at an angle with respect to one another.

2. Implant as claimed in claim 1, characterized in that the disk is designed as annular disk (35, 45, 53), having regular or irregular circumference, and that the inner circumference of the disk has a polygonal or irregular cross-section.

3. Implant as claimed in claim 1 or 2, characterized in that the contact surfaces of the disks (14, 25, 53) have roughness, pore undulations, or other unevennesses.

4. Implant as claimed in claim 1, characterized in that the contact surfaces of the disks (14, 35, 53) have protruding tips or spikes (20).

5. Implant as claimed in one of the preceding claims, characterized in that the disk (45) has channels (46) into which bone cement or bone material can be introduced.

6. Implant as claimed in one of the preceding claims, characterized in that the disks (11 thru 14, 21, 35, 45, 53) consist of fiber-reinforced plastic, and are made within the framework of the winding method or of wound up [batched up] fiber mats [fiber webs].

7. Implant as claimed in one of the preceding claims, characterized in that the disk (53) is cut out of a strand (32, 33, resp. 50).

8. Implant as claimed in claim 7, characterized in that the strand [hank; rope] (32, 33 or 50) consists of unidirectional fibers (32 and/or braiding layers (31, 51).

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The USPTO Translator (GERMAN & Germanic languages)
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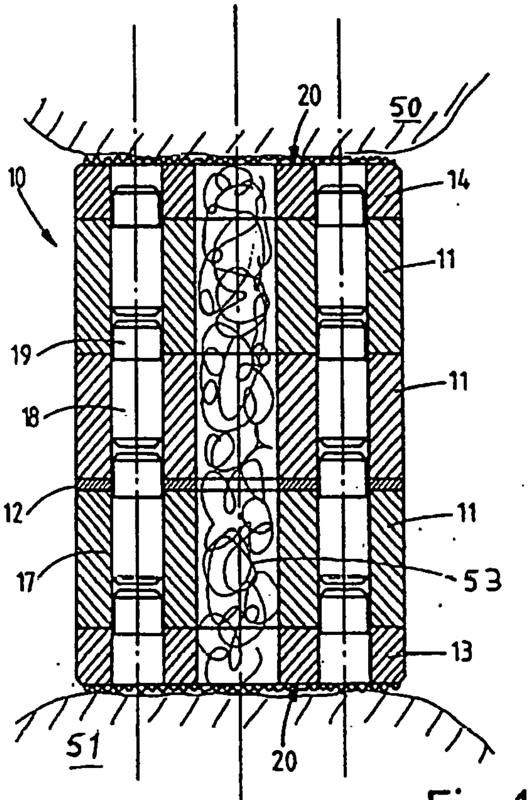

Fig.1

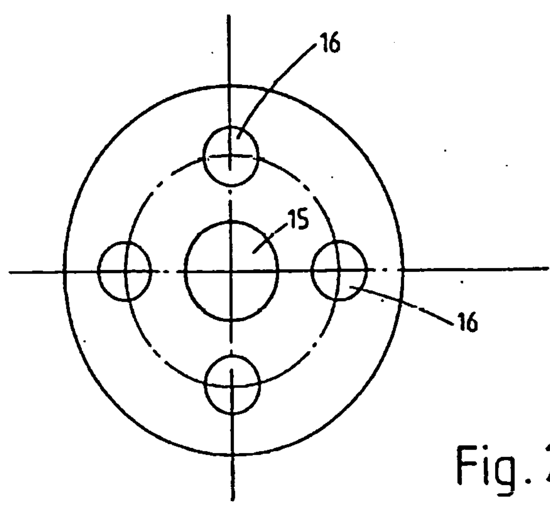

Fig. 2

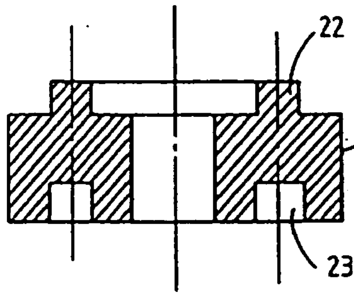

Fig. 3

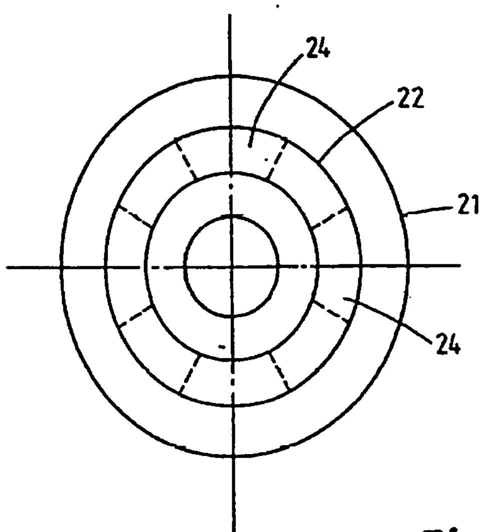

Fig. 4

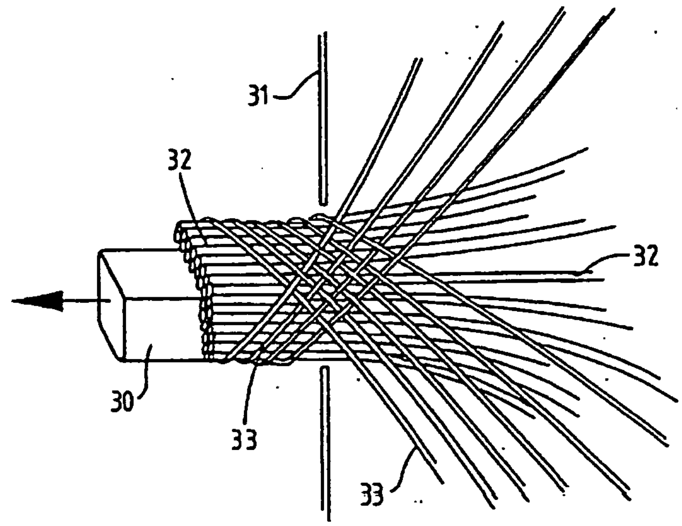

Fig. 5

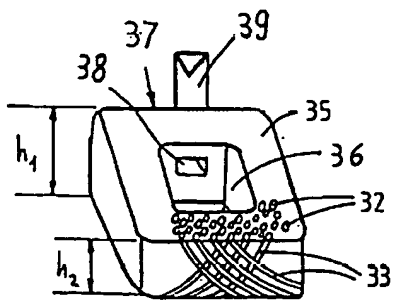

Fig. 6

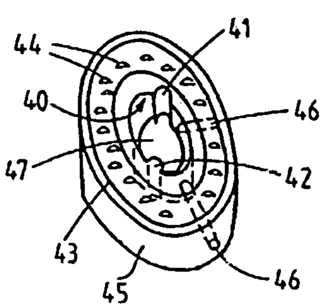

Fig. 7

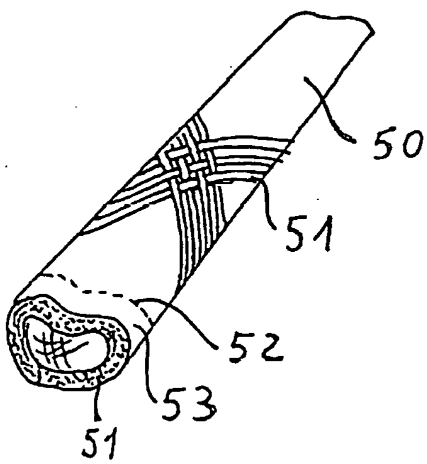

Fig.8